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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: CELEBREX MARKETING SALES PRACTICES AND PRODUCT LIABILITY LITIGATION

Case No. M:05-CV-01699-CRB

MDL No. 1699

THIS PLEADING RELATES TO:

Aurora Balloveras v. Pfizer, Inc., Case No.: 05-20429-CIV-JORDAN/BROWN (S.D. Fla.)

Dorothy Greaves v. Pfizer, Inc., et al., Case No.: 05-cv-647 (D. Ariz.)

Frankenmuth Fin. Group, et al. v. Pfizer, Inc., et al., Case No.: 05-71656 (E.D. Mich.)

Health Care for All, et al. v. Pfizer, Inc., et al., Case No.: 05-10707 RCL (D. Mass.)

June Swan, et al. v. Pfizer, Inc., et al., Case No.: 05-00834EDL (N.D. Cal.)

North Carolina Fair Share, et al. v. Pfizer, Inc., et al., Case No.: C05-03976-MMC (N.D. Cal.)

Sheet Metal Workers Local No. 20 Welfare & Benefit Fund, et al. v. Pfizer, Inc., et al., Case No.: 1:05-cv-1109-JDT-TAB (S.D. Ind.)

Sheet Metal Workers' Int'l Ass'n Local No. 28 of Metro. New York & Long Island, Case No.: 05 cv 4125 (S.D.N.Y.)

Betty A. Alexander, et al. v. Pfizer, Inc., et al., Case No.: 05-cv-01720-ML-ALC

National Health Ins. Co. v. Pfizer, Inc., et al., Case No.: 05-cv-04073 (N.D. Cal.)

THIRD AMENDED PURCHASE CLAIMS MASTER CELEBREX COMPLAINT

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I. NATURE OF THIS ACTION

A. Procedural Introduction

1. This Master Complaint is submitted to serve the administrative functions of efficiency and economy and to present certain common claims and common questions of fact and law for appropriate action by this Court in the context of this Multidistrict proceeding. This Master Complaint does not include all claims asserted in all of the purchase claims actions that have been transferred to this Court under 28 U.S.C. § 1407. Those matters are set forth in the individual and class actions filed by purchase claims Plaintiffs and served against Defendants. This Master Complaint does not constitute a waiver or dismissal of said actions or the claims asserted therein.

2. This Class Action is brought by and on behalf of all Consumers and Third-Party Payors (Consumers and Third-Party Payors are referred to herein collectively as "Plaintiffs," "Class Members," and "End-Payors") who purchased or paid for the prescription drug Celebrex ("Celebrex"), an anti-inflammatory drug researched, manufactured, marketed, promoted, advertised, sold, and distributed by Defendants Pfizer, Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle & Co. ("Searle").

3. Pursuant to Rule 23(a), 23(b)(1), 23(b)(2), 23(b)(3), and/or 23(c)(4)(A) of the Federal Rules of Civil Procedure, Plaintiffs will seek certification of a national End-Payor purchase claims class, through one or more actions transferred to or filed in this Court in the MDL 1699 litigation, consisting of:

> All End-Payors located in the United States, including Consumers and Third-Party Payors,[1] who purchased and/or paid for Celebrex not for resale during the period from December 1, 1998 through the present.[2]

4. Alternatively, in the event that this Court determines that a national End-Payor purchase claims class would not satisfy the requirements for class certification pursuant to Fed. R. Civ. P. 23, Plaintiffs would move for the certification of individual state class actions, grouped

[1] Third-Party Payors include all entities that: (a) provide, sponsor or insure a healthcare plan, which includes prescription drug coverage to natural persons, and (b) purchase, pay or insure all or part of the cost of prescription drugs prescribed and dispensed to those persons pursuant to a health plan.

[2] For further refinement of the class definition *see* Section VI, *infra*.

according to commonalities of state law consisting of, as to each state for which certification is sought:

> All End-Payors located in [State], including consumers and Third-Party Payors, who purchased and/or paid for Celebrex not for resale during the period from December 1, 1998 through the present.

5. In the event that Plaintiffs are directed to pursue the statewide class course of action set forth in the forgoing paragraph, Plaintiffs intend to request the Panel for Multi-District Litigation ("MDL Panel" or "Panel") to remand, to its transferor forum, each state class action as to which Plaintiffs seek certification, solely for purposes of addressing the class certification question. Remand of the class certification question will allow appellate review of the statewide class certification question by the appropriate Circuit Court(s), thus ensuring that no party will have been prejudiced by the Panel's random selection of a transferee forum whose procedural jurisprudence would determine the class certification issue differently from that of the transferor forum that is charged with its ultimate trial. For purposes of uniformity and judicial efficiency, Plaintiffs would further move the MDL Panel to appoint this Court to sit, by *ad hoc* designation, over the class certification issue in each transferor court as to which such remand is sought.

B. Summary of Allegations

6. Non-steroidal anti-inflammatory drugs ("NSAIDs") have been widely used to treat arthritis and pain for nearly 40 years. The pain relief offered by such NSAIDs comes at the expense of important adverse effects, most notably gastrointestinal toxicity. Use of NSAIDs leads to admission to hospital for ulcer complications (bleeding and perforation) in around 1% of users annually and results in thousands of deaths every year.

7. In 1989, scientists made a breakthrough in understanding how NSAIDs worked. Cyclo-oxygenase, the enzyme inhibited by NSAIDs, exists in at least two forms in the body. Traditional NSAIDs inhibit both the cyclo-oxygenase 2 enzyme ("COX-2"), which is inducible and expressed at sites of inflammation and the COX-1 enzyme, which is constitutive and expressed in the gastrointestinal ("GI") system. Inhibition of the COX-2 enzyme decreases inflammation and alleviates pain. Inhibition of the COX-1 enzyme, however, decreases the protection in the GI tract. Defendants leapt at this new understanding, hoping to create a new breed of NSAID that alleviated

pain, but did not have the GI toxicity associated with traditional NSAIDs. Defendants believed that this drug could be a blockbuster with yearly sales in the billions of dollars.

8. Celebrex was Defendants' first attempt to develop a drug that lived up to this dream. Defendants' scientists were never able to establish, however, that Celebrex was any more efficacious or safe than traditional NSAIDs. To the contrary, studies showed risks for gastrointestinal and cardiovascular ("CV") adverse event rates similar to or greater than traditional NSAIDs. The FDA approved label warned of GI and CV risks similar to traditional NSAIDs. Even so, as part of the unlawful scheme set forth below, Defendants embarked on a massive marketing campaign directed to both doctors and consumers to market Celebrex as a "breakthrough" drug clinically superior to and safer than older and far less expensive NSAIDs.

9. Defendants falsely represented that Celebrex provided symptomatic relief similar to ibuprofen and naproxen but was clinically superior because it had GI benefits and was the superior alternative for pain relief. For instance, traditional NSAIDs can, in a limited group of patients, cause gastrointestinal perforations, ulcers and bleeding. Defendants falsely promoted Celebrex as a safe and effective alternative that would have less deleterious and painful impacts on the gut than traditional NSAIDs. These representations violated the scope of the FDA's approval for the marketing of Celebrex.

10. Facing a rising tide of data that selective NSAIDs as a class posed cardiovascular risks, Defendants falsely claimed that Celebrex had cardiovascular benefits over alternative NSAIDs. Defendants made representations that Celebrex, in order to distinguish it from other NSAIDs, had "Cardiovascular Benefits" and had an "Established Cardiovascular Safety Profile," even though its FDA approved labeling contained the precaution, "[a]s with other NSAIDs, CELEBREX should be used with caution in patients with fluid retention, hypertension, or heart failure," and listed multiple, observed cardiovascular adverse events. After the withdrawal of Vioxx, another selective NSAID, Defendants, in an attempt to win over patients who had previously been on Vioxx, even attempted to convince doctors that Celebrex was cardioprotective. These cardioprotective claims were not authorized by the FDA and violated the scope of the FDA's approval as to the marketing of Celebrex.

11. Defendants made these claims despite the fact that the FDA, when it approved Celebrex, expressly warned that any advertising or promotional activity will be considered false and/or misleading if it suggests or represents any claims of safety beyond what was demonstrated in clinical trials and in the approved labeling. The labeling did not allow for claims of GI superiority or CV benefits, did not allow for cardioprotective claims and today contains black box warnings for both cardiovascular and gastrointestinal risk.

12. The extent to which a drug is paid for by Third-Party Payors is determined by that drug's status on the Third-Party Payor's "formulary," which is a list of drugs that plan participants are authorized to purchase for payment under the benefit plan. Placement of a prescription drug on the formularies of Third-Party Payors, medical care organizations, and or prescription benefit managers (who are employed by the Third-Party Payors to design or administer the benefit plans) is critical to the success of the drug. Defendants knew that preferred placement on these formularies would guarantee commercial success for Celebrex.

13. In an elaborate and sophisticated manner, Defendants aggressively marketed Celebrex directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on Third-Party Payors, medical care organizations, and large institutional buyers (*e.g.*, hospitals) to include Celebrex on their formularies. Faced with the increased demand for the drug by consumers and health care professionals that resulted from Celebrex's successful advertising and marketing blitz, Third-Party Payors were compelled to add Celebrex to their formularies. Celebrex's marketing campaign specifically targeted Third-Party Payors, physicians, and consumers, and was designed to convince all of these groups of both the therapeutic and economic value of Celebrex.

14. Defendants' marketing and promotion of Celebrex was part of a scheme to falsely create the impression and demand for Celebrex as a wide-ranging pain reliever that would enhance consumers' abilities to both live a normal life or engage in activities such as running, playing a guitar, swimming, walking, taking exercise classes and a host of similar activities that many who suffer from chronic pain have difficulty performing and get relief from acute pain following surgery.

15. The scheme was accomplished by unlawful means including, but not limited to: the false promotion of the CV safety or cardioprotective benefits of Celebrex; when in fact (a) the Celebrex label at all relevant times contained precautions regarding the potential for CV adverse events, (b) even though the warnings in the label grew stronger over time, culminating in a black box cardiovascular warning in July 2005, the Defendants' promotion of Celebrex as cardiovascularly safe or protective actually became increasingly ardent, including the promotion of Celebrex as cardioprotective, when the Defendants had clear scientific signals of cardiovascular adverse event risk. The scheme also included manipulation of data in an effort to show a GI benefit. The scheme featured a claim that Celebrex "when used for 6 months…is associated with a lower incidence of combined clinical upper GI events than comparator NSAIDs (ibuprofen and diclofenac) used at standard therapeutic dosages" [JAMA.2000;284:1247-1255] when in fact: (a) the prespecified endpoint of the CLASS trial had been specifically defined as "Clinically Significant Upper Gastrointestinal Events" not the combination of symptomatic and serious complications reported as the endpoint in the JAMA report of the CLASS study;[3] (b) the study lasted 12 not six months; (c) even during the first six months of the study reported in JAMA patients taking Celebrex did not develop significantly fewer serious GI complications than those taking older NSAIDs; and (d) in fact, use of Celebrex for more than six months ***increased*** the risk of GI complications; (iii) the manipulation of data to give the appearance of superiority over NSAIDs in pain efficacy and safety when such superiority did not exist; (iv) false promotional materials directed to doctors, third party payors and consumers concerning GI benefits and cardiovascular safety; and (v) the use of reprinted articles from prestigious medical journals that falsely claimed Celebrex was proven to be safer than NSAIDs.

16. From 1999 through 2003, Defendants spent approximately $400 million on direct-to-consumer advertising for Celebrex. This expensive marketing effort paid off. Celebrex set an all time record for the shortest time from synthesis of the drug molecule to $1 billion in sales. In

[3] "The definition of CSUGIEs [is that] chosen by the sponsor is…. This is a clinically meaningful definition and represents a major advance in the study of UGI toxicity of NSAIDs." From Medical Officer's Gastroenterology Advisory Committee Briefing Document, Lawrence Goldkind MD, **http://www.fda.gov/ohrms/dockets/ac/01/briefing/3677b1_05_gi.doc**.

2004, Celebrex achieved $3.3 billion in worldwide sales, 82% of which occurred in the United States[4/5] (the US and New Zealand – with a population of less than 4 million – are the only two industrialized countries that allow direct-to-consumer advertising). In 2004, Celebrex accounted for 6.3% of Pfizer's total worldwide sales of $52.5 billion.

17. As a result of Defendants' scheme, they were able to create a market for Celebrex and to sell Celebrex at a premium price over traditional NSAIDs and to have it become a standard treatment option as opposed to use of less expensive NSAIDs. Also part of Defendants' scheme was their role in the publication of the American College of Rheumatology's guidelines for the treatment of osteoarthritis of the hip and knee issued in September, 2000. These guidelines called for the use of Celebrex or Vioxx if acetaminophen failed to provide adequate relief. Three out of the four authors had financial ties to the Defendants at the time these guidelines were written and such claims were not scientifically supported or approved by the FDA.

18. The success of Defendants' scheme was recently documented in a study released on January 24, 2005, in the ARCHIVES OF INTERNAL MEDICINE, Volume 165, entitled *National Trends in Cyclooxygenage-2 Inhibitor Use Since Market Release*. The authors of that study concluded that the "aggressive marketing techniques to patients and physicians" caused a growth not only in use of COX-2 inhibitors but also in overall market demand.

19. In fact, Celebrex has been promoted as a superior pain reliever when for most patients it has no proven superiority over other NSAIDs. Celebrex sells for $2.53 to $6.45 per day depending upon the dose, while NSAIDs sell for $0.21 to $0.31 per day. Billions of dollars have thus been wasted in which Plaintiffs and Class Members have paid a premium price for a drug that is not a premium or superior product over equally available NSAIDs and other pain medications. If Defendants had not engaged in the wrongful marketing, advertising and promotion of Celebrex, Plaintiffs and Class Members would have paid for other equally effective and less expensive medications or made no purchase at all. Had the truth been told about its safety and efficacy,

[4] $2.7 billion in US sales in 2004: http://money.cnn.com/2006/01/17/news/companies/pfizer/.

[5] $3.3 billion in worldwide sales in 2004: http://www.pfizer.com/pfizer/annualreport/2004/financial/financial2004.pdf.

Celebrex would have sold at a price similar to that of far less expensive traditional NSAIDs and would not have become a standard in the treatment of arthritis and other forms of pain relief. The study in the ARCHIVES OF INTERNAL MEDICINE found that 63% of patients who received COX-2 inhibitors were at a low risk for developing the ulcers and GI problems that the COX-2 inhibitors were aimed at preventing (*i.e.*, they did not need Celebrex), and that Defendants' marketing scheme had played a significant role in over use of COX-2 inhibitors for this type of patient. In fact, the ARCHIVES study understates the lack of a need for Celebrex. A Federal Drug Administration ("FDA") reviewer found that Celebrex "did not appear to offer a unique advantage to high-risk patients." Thus in both the non-risk and at-risk population, Celebrex was neither more effective nor safer than other NSAIDs.

20. In this action Plaintiffs seek damages arising from the purchases of Celebrex resulting from Defendants' illegal scheme and/or conduct.

II. JURISDICTION

21. This Court has subject-matter jurisdiction over this class action pursuant to the Class Action Fairness Act of 2005, which, *inter alia*, amends 28 U.S.C. § 1332 to add a new subsection (d) conferring federal jurisdiction over class actions where, as here, "any member of a class of plaintiffs is a citizen of a State different from any defendant" and the aggregated amount in controversy exceeds five million dollars ($5,000,000). *See* 28 U.S.C. §§ 1332(d)(2) and (6). This Court has personal jurisdiction over the parties because Plaintiffs submit to the jurisdiction of the Court and Defendants systematically and continually conduct business throughout the State of California, including marketing, advertising, and sales directed to California residents.

III. PARTIES

A. Plaintiffs

22. Plaintiff Aurora Balloveras ("Balloveras"), who filed Civil Action No. 05-20429-CIV-JORDAN/BROWN (S.D. Fla.), is a resident of Miami-Dade County, Florida, and is otherwise *sui juris*. During the proposed Class Period, Balloveras was prescribed, purchased and consumed Celebrex within the state of Florida based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

23. Plaintiff Bricklayers of Indiana Welfare Fund ("Bricklayers"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 9045 East 59th Street, Indianapolis, Indiana 46219. Bricklayers is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). Bricklayers is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

24. Plaintiff Commonwealth Care Alliance ("CCA"), who filed Civil Action No. C05-03976-MMC (N.D. Cal.), is a prepaid care system contracting with Medicare and Massachusetts Medicaid to provide comprehensive care to vulnerable, high-cost populations. It is located in Boston, Massachusetts. CCA is a Third-Party Payor that paid for Celebrex on behalf of its beneficiaries during the relevant time period, and was injured by the illegal conduct described in this Complaint. CCA has standing to bring this action on behalf of itself and all other Third-Party Payors who paid for Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

25. Plaintiff Frankenmuth Financial Group, Inc. ("Frankenmuth"), who filed Civil Action No. 05-71656 (E.D. Mich.), is an entity maintaining its principal place of business at Frankenmuth, Michigan. Frankenmuth (or its members) has paid for purchases of Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

26. Plaintiff Dorothy Greaves ("Greaves"), who filed Civil Action No. 05-cv-647 (D. Ariz.), is a resident of Arizona. She purchased Celebrex in Arizona. Had she known the truth about Celebrex, she would not have purchased it and/or certainly not at the price she paid when it was substantially inflated. Greaves pursues this class action on behalf of herself and all others

similarly situated based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

27. Plaintiff Sarah Hare ("Hare"), who filed Civil Action No. 05-00834EDL (N.D. Cal.), is an individual residing in California. Plaintiff Hare purchased Celebrex and was injured by the illegal conduct alleged herein. Specifically, she has taken Celebrex for approximately four years in the treatment of lower back and hip pain. She pays co-payments through her insurance plan. As an individual, Plaintiff Hare pursues this class action on behalf of herself and all those similarly situated based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

28. Plaintiff Beatrice Howard ("Howard"), who filed Civil Action No. 05-00834EDL (N.D. Cal.), is an individual residing in California. Plaintiff Howard purchased Celebrex and was injured by the illegal conduct alleged herein. Specifically, she took Celebrex for approximately three years to treat arthritis. She paid co-payments through her insurance plan. As an individual, Plaintiff Howard pursues this class action on behalf of herself and all those similarly situated based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

29. Plaintiff IBEW 673 Fringe Benefit Funds Fund ("IBEW 673"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 8358 Munson Road, Mentor, Ohio 44060. IBEW 673 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). IBEW 673 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

30. Plaintiff IBEW Local 32 Health and Welfare Fund ("IBEW 32"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of

business at 1975 North West Street, Lima, Ohio 45801. IBEW 32 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. IBEW 32 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

31. Plaintiff IBEW Local 129 Fringe Benefit Funds ("IBEW 129"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 36964 Detroit Road, Avon, Ohio 44011. IBEW 129 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. IBEW 129 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

32. Plaintiff IBEW Local 683 Fringe Benefit Funds ("IBEW 683"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 23 West Second Avenue, Columbus, Ohio 43201. IBEW 683 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. IBEW 683 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

33. Plaintiff Indiana Carpenters Health and Welfare Fund ("ICHWF"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 2635 Madison Avenue, Indianapolis, Indiana 46225. ICHWF is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. ICHWF is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

34. Plaintiff Indiana Electrical Workers Benefit Trust ("IEWBT"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 1828 N. Meridian Street, Suite 103, Indianapolis, Indiana 46202. IEWBT is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. IEWBT is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

35. Plaintiff Indiana State District Council of Laborers and Hod Carriers Welfare Fund ("ISDC"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 413 Swan Street, Terre Haute, Indiana 47807. ISDC is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. ISDC is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the

cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

36. Plaintiff Indiana State Council of Roofers Health and Welfare Fund ("Roofers"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 1345 Northside Boulevard, South Bend, Indiana 46615. Roofers is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. Roofers is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

37. Plaintiff Georgia Katsanos ("Katsanos"), who filed Civil Action No. 05-00834EDL (N.D. Cal.), is an individual residing in California. Plaintiff Katsanos purchased Celebrex and was injured by the illegal conduct alleged herein. Specifically, she has taken Celebrex for at least four years. She paid co-payments through her insurance plan. As an individual, Plaintiff Katsanos pursues this class action on behalf of herself and all those similarly situated based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

38. Plaintiff National Healthcare Insurance Company, who filed Civil Action C05-04073 (N.D. Cal.) is a life and health insurance company with its principal place of business at 1901 North State Highway 360, Grand Prairie, Texas 75050, and is involved in the business of providing health benefits, among others, to covered lives. Plaintiff paid for prescriptions Celebrex dispensed to covered lives in several states. Plaintiff has paid and provided, and will in the future pay and provide, health care benefits to its members and insureds as a direct result of the wrongful conduct of Defendant as fully alleged herein.

39. Plaintiff Rose Lohman ("Lohman"), who filed Civil Action No. 05-05-10707 RCL (D. Mass.), has been taking Celebrex for ten years, has paid for Celebrex and has been injured as a

result based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

40. Plaintiff Michelle Madoff ("Madoff"), who filed Civil Action No. 05-10707 RCL (D. Mass.), is a resident of the State of Arizona. Until recently Madoff took Celebrex and has made out-of-pocket payments for Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

41. Plaintiff Helen Marconi ("Marconi"), who filed Civil Action No. C05-03976-MMC (N.D. Cal.), is a resident of Bronx, New York. During the relevant time period, she purchased Celebrex and was injured by the illegal conduct described in this Complaint based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

42. Plaintiff Robert Mariconi ("Mariconi"), who filed Civil Action No. C05-03976-MMC (N.D. Cal.), is a resident of Saddle Brook, New Jersey. During the relevant time period, he purchased Celebrex and was injured by the illegal conduct described in this Complaint based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

43. Plaintiff Evelyne Mayes ("Mayers"), who filed Civil Action No. C05-03976-MMC (N.D. Cal.), is a resident of Indianapolis, Indiana. During the relevant time period, she purchased Celebrex and was injured by the illegal conduct described in this Complaint based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

44. Plaintiff Judith C. Meredith ("Meredith"), who filed Civil Action No. 05-10707 (D. Mass.), is a resident of the Commonwealth of Massachusetts residing in Dorchester, Massachusetts. During the relevant period, Meredith purchased Celebrex and was injured by the illegal conduct described in this Complaint. Specifically, she began taking Celebrex approximately two years ago to treat pre-arthritis pains. She had previously taken ibuprofen. She began taking Celebrex after seeing the advertisements and asked her doctor to prescribe it for her. She has paid

co-payment amounts to purchase Celebrex through her prescription drug coverage plan provided through her husband's employer. As an individual, Meredith pursues this class action on behalf of herself and those similarly situated based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

45. Plaintiff Michiana Area Electrical Workers Health and Welfare Fund ("Michiana"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 1345 Northside Boulevard, South Bend, Indiana 46615. Michiana is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. Michiana is a non-profit trust, sponsored and administered by the Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

46. Plaintiff Mary Morris ("Morris"), who filed Civil Action No. C05-03976-MMC (N.D. Cal.), is a resident of Fort Wayne, Indiana. During the relevant time period, she purchased Celebrex and was injured by the illegal conduct described in this Complaint based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

47. Plaintiff New England Carpenters Health Benefits Fund ("Carpenters"), who filed Civil Action No. C05-03976-MMC (N.D. Cal.), is an employee welfare benefit plan established and maintained pursuant to sections 1002(1) and (3) of ERISA, for the purposes of providing health benefits to eligible participants and beneficiaries. As such, Carpenters is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). Carpenters maintains its principal place of business in Wilmington, Massachusetts. It provides comprehensive health coverage for over 22,000 participants and beneficiaries in the states of Maine, New Hampshire, Vermont and Massachusetts. Carpenters is a Third-Party Payor that paid for Celebrex on behalf of its beneficiaries during the relevant time period, and was injured by the illegal conduct described in

this Complaint. Carpenters has standing to bring this action on behalf of itself and all other Third-Party Payors who paid for Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

48. Plaintiff Painters Local No. 469 Health and Welfare Fund ("Painters 469"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 7730 North 500 East, Decatur, Indiana 46615. Painters 469 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. Painters 469 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

49. Plaintiff Painting Industry Insurance and Annuity Funds ("PIIAF"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 8257 Dow Circle, Cleveland, Ohio 44136. PIIAF is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. PIIAF is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

50. Plaintiff Pipe Trades Industry Health and Welfare Plan ("Pipe Trades"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 8838 East Milner, Terre Haute, Indiana 47803. Pipe Trades is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. Pipe Trades is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining

by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

51. Plaintiff Plumbers and Steamfitters Local 42 Health & Welfare Plan ("Plumbers 42"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 187 Woodlawn Avenue, Norwalk, Ohio 44857. Plumbers 42 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. Plumbers 42 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

52. Plaintiff Plumbers and Steamfitters Local No. 166 Health and Welfare Plan ("Plumbers 166"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 2930 West Ludwig Road, Fort Wayne, Indiana 46818. Plumbers 166 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. Plumbers 166 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

53. Plaintiff Plumbers Local No. 210 Health and Welfare Fund ("Plumbers 210"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 2901 East 83rd Place, Merrillville, Indiana 46410. Plumbers 210 is an

"employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. Plumbers 210 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

54. Plaintiff Service Employee International Union Local No. 3 Health & Welfare Fund ("Service Employee"),who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 1735 East 23rd, Cleveland, Ohio 44114. Service Employee is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. Service Employee is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

55. Plaintiff Sheet Metal Workers Local No. 20 Welfare and Benefit Fund ("Sheet Metal 20"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity maintaining its principal place of business at 2828 East 45th Street, Indianapolis, Indiana 46220. Sheet Metal 20 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in ERISA. Sheet Metal 20 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

56. Plaintiff Sheet Metal Workers' International Association Local No. 28 of Metropolitan New York & Long Island ("Sheet Metal 28"), who filed Civil Action No. 05 cv 4125 (S.D.N.Y.), is a labor union health and welfare fund that provides health and prescription drug benefits to its member in Metropolitan New York and Long Island, and specifically, it has paid or reimbursed members for prescription drug benefits including for the purchase of the drug Celebrex. Sheet Metal 28 is headquartered in Mineola, New York. Sheet Metal 28 (or its members) purchased Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

57. Plaintiff Southern Ohio Painters Health and Welfare Fund ("S. Ohio"), who filed Civil Action No. 1:05 01-cv 1109 JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 2621 East Third Street, Dayton, Ohio 45403. S. Ohio is an "employee welfare benefit plan" as defined in ERISA. S. Ohio is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

58. Plaintiff Steamfitters' Industry Welfare Fund ("Steamfitters"), who filed Civil Action No. 05 cv 3814 (S.D.N.Y.), is a union health and welfare fund that provides health and prescription drug benefits to its members, and specifically, it has paid or reimbursed members for prescription drug benefits for Bextra for its members and was injured by the illegal conduct alleged herein. Steamfitters is headquartered in the city of New York, in the State of New York.

59. Plaintiff June Swan ("Swan"), who filed Civil Action No. 05-00834EDL (N.D. Cal.), is an individual residing in California. Plaintiff Swan purchased Celebrex and was injured by the illegal conduct alleged herein. Specifically, she has taken Celebrex for approximately two years in the treatment of arthritis and hip pain. She pays co-payments through her insurance plan. As an individual, Plaintiff Swan pursues this class action on behalf of herself and all those

similarly situated based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

60. Plaintiff Linda A. Watters, Commissioner ("Watters"), who filed Civil Action No. 05-71656 (E.D. Mich.), Offices of Financial and Insurance Services for the State of Michigan in her capacity as Rehabilitator of The Wellness Plan and in her capacity as Liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known as OmniCare Health Plan, Inc., is a Michigan official whose function is to collect and liquidate all assets and liabilities of the former private Third-Party Payors Wellness Plan and OmniCare. At all times relevant to this Complaint, Wellness Plan and OmniCare were private Third-Party Payors whose function was to assume the risk of payment of medical and prescription costs on behalf of the participants in its plan. Wellness Plan and Omnicare paid for purchases of Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

61. Plaintiff Stephen Keisker is a resident of Danville, Hendricks County, Indiana. Mr. Keisker paid for the entire cost of his Celebrex prescription out-of-pocket. He took Celebrex between 1999 and 2001 and was economically injured as described herein.

62. Plaintiff Betty A. Alexander, who filed Civil Action No. 05-1720 (E.D. La.), is a person of the full age of majority domiciled in Orleans Parish, Louisiana, and is a Louisiana consumer who paid for the prescription drug Celebrex.

63. Plaintiff Allied Services Division Welfare Fund ("ASD"), who filed Civil Action No. 05-1720 (E.D. La.), is a health and welfare benefit fund with its principal place of business at 53 West Seegers Road, Arlington Heights, Illinois 60005, and is involved in the business of providing health and pension benefits, among others, to covered lives. ASD is a multi-employer employee welfare benefit plan within the meaning of ERISA U.S.C. § 1001(2), and § 1002(37). ASD paid for prescriptions of Celebrex dispensed to covered lives in several states. ASD has paid and provided, and will in the future pay and provide, health care benefits to its members and insureds as a direct result of the wrongful conduct of the Defendant as fully alleged herein.

64. Each of the Plaintiffs (or its members) purchased Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

B. Defendants

65. Defendant Pharmacia is a Delaware corporation with its principal place of business in New Jersey. At all relevant times, Pharmacia has been engaged in the business of marketing and selling Celebrex nationwide.

66. Defendant Pfizer is a Delaware corporation with its principal place of business in New York. In 2003, Pfizer acquired Pharmacia for nearly $60 billion. During the relevant time period, Pfizer has been engaged in the business of marketing and selling Celebrex nationwide.

67. Defendant Searle is a Delaware corporation with its principal place of business in Illinois. At all relevant times, Searle has been engaged in the business of marketing and selling Celebrex nationwide.

68. G.D. Searle was the discoverer and developer of Celebrex. In 1999, Searle and Pfizer joined forces to co-promote Celebrex. Thereafter, Pharmacia acquired Searle in 2000 and Pharmacia merged with Pfizer on April 16, 2003.

IV. FACTUAL BACKGROUND

A. Development of Celebrex

69. Celebrex was the first prescription drug on the market in a new class of pain medications called "selective" NSAIDs. Aspirin and ibuprofen are examples of well-known non-selective NSAIDs.

70. NSAIDs reduce pain by blocking the body's production of pain transmission enzymes called cyclooxygenase or "COX." There are at least two forms of COX enzymes relevant to NSAIDs, COX-1 and COX-2.

71. COX-1 is constitutively expressed in most tissues throughout the body, including the gastrointestinal tract, kidney and platelets.

72. COX-2, is inducible, and is normally found in very low amounts in healthy tissue (except the brain and kidney), but is prominently expressed in inflamed tissues. COX-2 is not expressed in the platelets or the gut.

73. It is generally accepted in the medical community that blocking the COX-1 enzyme hampers the body's ability to repair gastric tissue and causes harmful gastrointestinal side-effects, including stomach ulceration and bleeding. In addition, blocking the COX-1 enzyme decreases the production of thromboxane in platelets, diminishing thromboxane's effect of vasoconstriction and platelet aggregation, and thereby increasing the risk of abnormal bleeding.

74. Traditional NSAIDs, like aspirin, reduce pain sensations by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs increase the risk of ulcers in the stomach and intestines. However, because of a complex chemical balance in the human body, traditional NSAIDs are not generally associated with blood clots, and aspirin even reduces the risk of clots and helps to protect heart function, an effect commonly referred to as "cardioprotection."

75. Selective NSAIDs, unlike traditional NSAIDs, inhibit COX-2 to a greater degree than COX-1. It is generally accepted in the medical community that blocking the COX-2 enzyme, without concurrent blocking of COX-1, encourages the formation of blood clots and increases the risk of various clot-related cardiovascular events, including: heart attack, stroke, unstable angina, cardiac clotting and hypertension.

76. Defendants, in deciding to pursue the development of these selective NSAIDs, either intentionally ignored or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostacyclin levels without a counterbalancing reduction in thromboxane production, thereby increasing the risk of blood clots and various clot-related cardiovascular and cardiorenal events.

77. For decades, in the absence of other treatment options, consumers seeking pain relief were forced to accept and live with the gastrointestinal risks of traditional NSAIDs or take nothing and live with the pain.

78. Defendants thought that by developing "selective" inhibitors that would block only COX-2 production, the proper maintenance of gastric tissue would remain while still reducing pain and inflammation.

B. Limited FDA Approval

79. Defendant Searle filed for FDA approval for Celebrex on June 29, 1998. In its pre-approval marketing plans, Defendants planned that Celebrex would be approved and that such approval would include an indication that it was safer than NSAIDs in protecting against GI complications.

80. Pre-approval marketing plans stressed that Celebrex was superior to NSAIDs and thus a "breakthrough" in science and safety. Pre-approval plans were to promote Celebrex as offering a significant reduction in GI complications.

81. The FDA expressly criticized Celebrex's pre-launch marketing. In a July 16, 1997 letter to Defendant Searle, the FDA warned that Searle was marketing celecoxib, an unapproved new drug, on its website www.searlehealth.com. Specifically, the FDA criticized the Defendants' claims that,

> celecoxib "does not interfere with protective prostaglandins in the stomach, intestines and kidney." Furthermore, the statement that celecoxib does not interfere with protective prostaglnadins combined with the statement that commonly prescribed arthritis medications cause gastrointestinal bleeding, suggests that celecoxib does not cause gastrointestinal bleeding.

The FDA further criticized a press release that appeared on the same website that proclaimed that the results of a Phase II study support Celebrex's safety and efficacy, stating "Searle has not demonstrated that celecoxib does not interfere with prostaglandins in the stomach, intestines, or kidney nor that it does not cause gastrointestinal bleeding." Finally, the FDA blasted Defendants promotion of celecoxib as a "Breakthrough" in arthritis therapy stating that such statements are "clearly violative of the Act." The FDA then recommended that Searle delete all references to celecoxib from its internet site.

82. Again on December 8, 1998, the FDA sent a letter to Defendants finding additional violative pre-approval promotions of Celebrex. Namely, the FDA found the following statements in a November 12, 1998 press release, improper:

> "As Effective as Naproxen and Diclofenac but with a Gastrointestinal Safety Profile Similar to Placebo."
>
> "Searle and Pfizer's investigational drug, relieved the signs and symptoms of arthritis as effectively as the full therapeutic doses of two of the most widely prescribed non-steroidal anti-inflammatory (NSAID) pain relievers in use today, but with a gastrointestinal (GI) safety profile similar to placebo"
>
> "Safety Profile Showed no Significant GI Safety Differences from Placebo"
>
> "In Clinical studies, celecoxib was as effective as the widely used NSAID naproxen in both RA and OA, but with a superior safety profile"

Although the FDA recommended that all such promotions should cease immediately, Defendants carried on with such promotions of the false safety of Celebrex through launch, and as demonstrated in detail below, throughout the Class Period.

83. These early preapproval marketing efforts were not approved in any fashion by the FDA, helped create demand for the product, and included claims that the FDA, when Celebrex was approved, did not allow the manufacturer to make.

84. In spite of early signals that selective NSAIDs posed CV risks, Defendants' initial marketing plan included the downplaying of any Celebrex CV risks and the promotion of Celebrex as cardiovascularly safer than traditional NSAIDs. Defendants did so through several means, including (1) skewing studies so that CV adverse events were less likely to occur or would less likely be seen in the data produced; (2) delaying publication or release of data to the FDA or otherwise complete failure to disseminate negative CV scientific data that would contradict Defendants fraudulent, off-label CV marketing campaign; (3) actively promoting the CV safety of Celebrex; and (4) touting the general safety superiority of Celebrex in the midst of CV concerns over selective NSAIDs in order to give the impression that Celebrex had a superior CV profile to other NSAIDs. After public concern began to grow regarding a potentially high CV risk for all

selective NSAIDs, Defendants continued to tout Celebrex as CV safe and even as cardioprotective in order to restore confidence in Celebrex and increase sales.

85. The FDA approved Celebrex for the treatment of osteoarthritis and rheumatoid arthritis on December 23, 1999, warning "any advertising and/or promotional activity of this product will be considered false and/or misleading…if it presents suggestions or representations that COX-2 selectivity confers on the product any claims of safety beyond what has been demonstrated in clinical studies and presented in the approved labeling."

86. Although Defendants had struggled for years to prove that Celebrex was safer on the GI tract, the FDA concluded that Celebrex had to retain the same GI warning in its label as traditional NSAIDs that serious gastrointestinal toxicity "can occur at any time, with or without warning symptoms, in patients treated with nonsteroidal anti-inflammatory drugs (NSAIDs)." In approving Celebrex for the treatment of osteoarthritis and rheumatoid arthritis, the FDA specifically warned Defendants that any promotional activities "that make or imply comparative claims about the frequency of clinically serious GI events compared to NSAIDs or specific NSAIDs will be considered false and/or misleading…." If the Defendants' marketing reflected their scientific knowledge of Celebrex or the FDA's conclusions regarding its safety and efficacy, this finding could have been a serious blow to their profits.

87. The FDA, on January 29, 1999, with respect to G.D. Searle's initial promotional materials, warned Searle that any ***suggestion*** of GI superiority was misleading, "because it is based on nonclinical data and is not supported by evidence approved on the label." It continued that failure to include the GI warning in any promotional material "would constitute an omission of material fact."

88. The original FDA approved label for Celebrex also included the precaution:

> ***Fluid Retention and Edema:***
> Fluid retention and edema have been observed in some patients taking CELEBREX (see ADVERSE REACTIONS). Therefore, CELEBREX should be used with caution in patients with fluid retention, hypertension, or heart failure.

The Adverse Reactions section lists the following potential CV adverse events "aggravated hypertension,…syncope, congestive heart failure, ventricular fibrillation, pulmonary embolism,

cerebrovascular accident, peripheral gangrene, [and] thrombophlebitis." The Defendants pre-launch and launch advertisements ignored these potential CV risks and instead promoted Celebrex as superior to alternative NSAIDs from a CV standpoint, a claim that is above and beyond and even contradicted by Celebrex's FDA approved label.

B. The CLASS Study

89. Defendants funded significant clinical trials hoping to demonstrate that Celebrex had greater gastrointestinal safety than traditional NSAIDs: the Celecoxib Long-Term Arthritis Safety Studies ("CLASS").

90. Defendants expected the CLASS study to show that Celebrex was statistically significant in reducing serious GI complication over NSAIDs and that the results would allow removal of the warning label. Removal of the warning label would in turn justify Defendants' GI superiority marketing campaign.

91. The CLASS trials were long-term, double-blind studies of gastrointestinal toxicity in 8,059 patients taking Celebrex, ibuprofen or diclofenac to treat arthritis. Patients with heart problems were allowed to participate in the CLASS trials, and were permitted to take low doses of aspirin to reduce the risk that they would suffer an adverse CV event during the study.

92. When the CLASS study was completed, the results were reported to the FDA's Arthritis Drugs Advisory Committee ("the Committee") as part of a request to exempt Celebrex from including the standard NSAID GI safety warning in its package insert. The Defendants attempted to frame the data so that it appeared that Celebrex was safer on the GI tract. The Defendants also hoped that the FDA did not notice the CV safety signals in the data as evidenced by a July 2001 "War Room" meeting at which the Defendants discussed preparations for the "worse case scenario (i.e. CV in the label)."

93. After reviewing the CLASS results, ***the Committee concluded that patients taking Celebrex had not experienced fewer gastrointestinal complications than those taking traditional NSAIDs***. In other words, CLASS showed that Celebrex failed to achieve its primary endpoint of reduced "clinically significant serious gastrointestinal events." Without evidence of enhanced safety, the Committee then recommended that the Celebrex label contain the same GI warnings as

traditional NSAIDs, and advised further studies to assess the risk of COX-2 inhibitors when taken with aspirin. Thus, Defendants' clinical studies did not have their intended effect: Celebrex was not permitted to claim increased GI safety over traditional NSAIDs.

94. The CV precaution in Celebrex's labeling was expanded to,

> Fluid Retention, Edema, and Hypertension: Fluid retention and edema have been observed in some patients taking CELEBREX (see ADVERSE REACTIONS). In the CLASS study…the Kaplan-Meier cumulative rates at 9 months of peripheral edema in patients on CELEBREX 400 mg BID (4-fold and 2-fold the recommended OA and RA doses, respectively, and the approved dose for FAP), ibuprofen 800 mg TID and diclofenac 75 mg BID were 4.5%, 6.9% and 4.7%, respectively. The rates of hypertension in CELEBREX, ibuprofen and diclofenac treated patients were 2.4%, 4.2% and 2.5%, respectively. As with other NSAIDs, CELEBREX should be used with caution in patients with fluid retention, hypertension, or heart failure.

A warning was added to the Drug Interactions section, stating,

> Because of its lack of platelet effects, CELEBREX is not a substitute for aspirin for cardiovascular prophylaxis.

The FDA also insisted that the following data regarding the withdrawals for serious adverse events be included on the Celebrex label:

> Kaplan-Meier cumulative rates at 9 months for withdrawals due to adverse events for CELEBREX, diclofenac and ibuprofen were 24%, 29%, and 26%, respectively. Rates for serious adverse events (i.e. those causing hospitalization or felt to be life threatening or otherwise medically significant) regardless of causality were not different across treatment groups, respectively, 8%, 7%, and 8%.
>
> Based on Kaplan-Meier cumulative rates for investigator-reported serious cardiovascular thromboembolic adverse events*, there were no differences between the CELEBREX, diclofenac or ibuprofen treatment groups. The rates in all patients at 9 months for CELEBREX, diclofenac and ibuprofen were 1.2%, 1.4%, and 1.1% respectively. The rates for non-ASA users in each of the three treatment groups were less than 1%. The rates for myocardial infarction in each of the three non-ASA treatment groups were less than 0.2%.
>
> * includes myocardial infarction, pulmonary embolism, deep venous thrombosis, unstable angina, transient ischemic attacks or ischemic cerebrovascular accidents.

These precautions were meant to further alert to doctors and patients the possible CV risks associated with Celebrex. The CLASS data, as interpreted by the FDA (and even with aspirin use

that could mask any CV safety signals), revealed that Celebrex had similar, if not greater, CV risk to patients than traditional NSAIDs.

95. Defendants, prior to the CLASS findings, had initiated extensive pre-release marketing campaigns to convey the uniform message that Celebrex provided effective relief of arthritis pain without the potential GI side-effects and CV risks of traditional NSAIDs.

C. The JAMA Publication of CLASS

96. The Defendants, irrespective of the conclusions reached by the FDA, manipulated the results of CLASS to make it appear to the medical community and the public at large that the trials had shown that Celebrex was safer than traditional NSAIDs on the GI tract. For instance, manipulated results of the CLASS study were published in the September 13, 2000 issue of JAMA.

97. Each of the Defendants played a role in the establishment of the CLASS trials and how the results were then portrayed to JAMA and to the medical community.

98. ***The article in JAMA concluded that Celebrex, "when used for 6 months ... is associated with a lower incidence of clinical upper GI events than comparator NSAIDs (ibuprofen and diclofenac)."*** The accompanying editorial supported this conclusion: "The results of this important study ... provide ***promising data*** to suggest that [Celebrex is] ... ***effective in reducing***, but not eliminating, the risk of symptomatic [minor] ulcers and [major] ulcer complications in the enormous number of individuals who might benefit from these drugs.…"

99. There was, however, one very large problem. The manufacturer's original research plan, as submitted to the FDA, had defined the duration of the CLASS study that compared Celebrex with ibuprofen as 12 months, and that of the study comparing Celebrex with diclofenac as 16 months. And, indeed, the combined study had run for a full 12 months. ***The authors, however, submitted only the first six months of data for the article in JAMA.*** Peer reviewers, editors, and editorialists had no way of knowing that the study had last for 12, not six, months. As a result, data from the ***second*** six months of the study were unreported and invisible to even the most careful readers of the JAMA article. The missing data invalidated the conclusions presented in the JAMA article: ***six of the seven serious gastrointestinal complications that occurred in the second half of the study were in patients taking Celebrex***.

100. Pharmacia had presented a statistical argument to the FDA justifying its omission of the data from the second half of its study. The company claimed that since a higher percentage of people taking diclofenac dropped out of the study because of minor symptoms like heartburn, the data from the second half of the study were invalid because of what is called "informed censoring." Pharmacia argued that these dropouts would have gone on to develop serious GI complications, and their dropping out of the study artificially minimized the risk of serious complications in the people taking diclofenac. The FDA flatly rejected this argument. It countered that there was no proof that the people with heartburn would have developed more serious GI problems. Further, the FDA GI reviewer concluded that if minor symptoms caused people in the study to stop taking diclofenac, people in the real world would similarly stop taking the drug if it caused heartburn and would similarly protect themselves from going on to develop serious GI complications.

101. The FDA's opinion of the manufacturer's decision to publish only half of the data from its study was clear: "[T]he sponsor's presentations of 6-month data ... are not statistically valid or supportable." The FDA's gastroenterology reviewer concluded that the first six months of data – which had been presented in the JAMA article as if they were a report of the entire study – were not worthy of separate consideration: "Based on the lack of adequate rationale, these post-hoc analyses will not be further discussed or presented in this review." Looking at the data from the entire year of the study, the FDA's gastroenterology reviewer concluded that "***the sponsor has failed to demonstrate a statistically significant lower rate" of serious GI complications in the people who took Celebrex compared with the people who took the other NSAIDs***. When the reviewer looked at only the second six months of data (*i.e.*, the data that had not been published in the JAMA article), he ***concluded that the risk of serious GI complications appeared to be higher in the people who took Celebrex "compared to <u>both</u> ibuprofen and diclofenac***" (emphasis in original). This was hardly an endorsement for a drug whose only advantage (besides the convenience of a once-daily dosing) was that it supposedly caused fewer serious GI problems.

102. The disparity between the Defendants public marketing of Celebrex and the information in the FDA's files by no means stopped there. The primary question that the CLASS study had been designed to answer had been changed, producing results that were far more

favorable to the manufacturer. The original research design submitted to the FDA by the manufacturer of Celebrex had stated: "The primary objective of this study is to compare the incidence of ***clinically significant*** [major] upper gastrointestinal events … in patients taking Celebrex to patients taking NSAIDs." The term "***clinically significant***" refers to complications that would generally require hospitalization: active bleeding, perforation of the stomach or duodenum requiring surgery, or obstruction of the outlet of the stomach. The research plan specifically called for the less serious gastrointestinal side effects to "be categorized and analyzed separately." Indeed the FDA's gastroenterology reviewer specifically commented that the plan to identify the "truly significant" serious gastrointestinal complications alone was a "major strength of the current study."

103. But when the results of the study were published in JAMA, the incidences of major and minor gastrointestinal complications were combined. Why the change? The results of the study as originally designed failed to show that the people who took Celebrex developed significantly fewer major GI complications than the people who took ibuprofen or diclofenac, even for just the first six months. ***Only by combining the minor GI symptoms with the more serious gastrointestinal complications could the article conclude that Celebrex caused a statistically significant decrease in gastrointestinal complications compared with the other NSAIDs***. As noted above, when the FDA looked at the results of the CLASS study in terms of the research question that had ***originally*** been posed, Celebrex was not significantly safer than the other NSAIDs.

104. Finally, the most important measure of safety is the overall frequency of serious side effects – including, but not limited to, GI side effects. For the full 12 months of the study, ***the people in the CLASS study who took Celebrex experienced 11 percent more serious complications*** (in all body systems combined) than the people who took the older and less expensive anti-inflammatory drugs. This difference did not reach statistical significance but certainly is significant in countering Pharmacia's claim that Celebrex is better than older NSAIDs because it is safer.

105. These findings contributed to the FDA's decision to send one of its rare "Warning Letters" to the CEO of Pharmacia in February 2001. The letter cites repeated unsubstantiated marketing claims that Celebrex is the preferred NSAID for people taking a blood thinner and that it is safe and effective for the treatment of acute pain – a use for which it was not approved – and points out that Pharmacia's marketing material fails to warn of the possibility of serious GI complications caused by the drug. The Warning Letter concludes by saying:

> Your promotional activities described above raise significant health and safety concerns in that they minimize crucial risk information and promote Celebrex for unapproved new uses. In two previous untitled letters dated October 6, 1999, and April 6, 2000, we objected to your dissemination of promotional materials for Celebrex that … contained unsubstantiated comparative claims, and lacked fair balance. Based upon your written assurances that this violative promotion of Celebrex had been stopped, we considered these matters closed. Despite our prior written notification, and notwithstanding your assurances, Pharmacia has continued to engage in false or misleading promotion of Celebrex.

106. Also included in the Warning Letter was the requirement that Pharmacia send out the "Dear Healthcare Provider" letter. Of course, the letter sent out by the manufacturer was not quite as specific as the FDA's Warning Letter. Few doctors, even if they had bothered to wade through the difficult language, had the time or inclination to find out the story behind the letter. As a result, ***doctors continue to this day to prescribe Celebrex for their patients based on the "scientific evidence" published in JAMA***, not understanding that it was incomplete and presented an inaccurate picture of the so-called safety advantage of Celebrex over other less expensive NSAIDs.

D. Use of the CLASS Study to Promote Sales of Celebrex

107. The JAMA article falsely concluded that Celebrex was associated with a lower incidence of complications than NSAIDs.

108. ***The flawed conclusions of CLASS, which were disputed by the FDA, were widely distributed and believed by physicians***. Tens of thousands of reprints of CLASS were bought from the publisher and a recent search of the Science Citation Index yielded 169 articles citing it, more than 10 times as many citations as any other article published in the same issue. The reprints were used by the Celebrex sales team to convince doctors that the "scientific evidence" showed that

Celebrex was safer for their patients than older, less expensive NSAIDs. The wide distribution of the JAMA article purporting to present the results of the CLASS study increased sales of Celebrex.

109. According to the BRITISH MEDICAL JOURNAL, Volume 324, June 1, 2002, many physicians still believe the CLASS study:

> Publishing and distributing overoptimistic short term data using post hoc changes to the protocol, while omitting disappointing long term data of two trials, which involved large numbers of volunteers, is misleading. While some of the problems related to CLASS were partially covered in the news sections of BMJ and other journals, it was not emphasized how flawed the trial actually was, and how inadequate the authors' justifications. Consequently, CLASS may still be relied on by many physicians without reference to these flaws. In our experience most still believe the findings published originally. For example, most of 58 physicians attending an osteoarthritis workshop in Berne, Switzerland, in December 2001 had not realized that CLASS was seriously biased.

110. The JAMA article was critical to the launch of Celebrex. Once a drug is introduced into the market and establishes itself at a certain price point, unless there is a withdrawal of the drug, the price point remains. By use of the incomplete study information published in JAMA, as well as other misleading statements, Defendants were able to establish the price of Celebrex.

E. Misleading Articles in Medical Journal Used to Establish Celebrex in the Marketplace

111. Defendants also used the placement of misleading articles in prestigious journals as a means to falsely promote Celebrex. Defendants placed articles, through paid consultants, in prestigious journals including JAMA, ARCHIVES OF INTERNAL MEDICINE and other publications.

112. An example is a "Special Article" appearing in ARTHRITIS & RHEUMATISM, Vol. 43, No. 9, September 2000, entitled *Recommendations for the Medical Management of Osteoarthritis of the Hip and Knees*. These guidelines, endorsed by the American College of Rheumatology (the professional society of arthritis specialists, became the gold standard for treatment of osteoarthritis ("OA"). Three out of four of the expert authors had financial relationships with Searle and Pharmacia. These guidelines state if non-pharmacologic therapies (like heat, ice, and physical therapy) fail to provide adequate relief from osteoarthritis pain, drug treatment should be initiated with acetaminophen (Tylenol). If acetaminophen provides inadequate relief, the next drugs recommended were COX-2 specific inhibitors, not other traditional NSAIDs. Without regard for

the proscription included in the FDA's new drug approval letter to Searle about Celebrex, the guidelines assert that COX-2 inhibitors, based on endoscopic studies, have an advantageous safety profile. The FDA's letter of December 31, 1998 addressing this issue stated:

> "… any promotional use of endoscopic data without the qualifying explanations of that data found in the approved labeling … will be considered false and misleading." [Label: The correlation between findings of endoscopic studies, and the relative incidence of clinically serious upper GI events that may be observed with different products, has not been fully established.]

Nonetheless, the authors of these guidelines concluded that COX-2 inhibitors, based on endoscopic studies, have an advantageous safety profile. Referring to the CLASS study, the authors noted that data from this study had not yet been published.

113. Medical journals that publish articles can add substantially to their income selling reprints to drug companies. Drug companies in turn give these reprints to their sales force who provide these to doctors as proof of a drug's superiority or qualities.

114. The publication of these guidelines established the use of COX-2 inhibitors as the standard drug therapy for the treatment of OA. Defendants purchased reprints of this article and it was used to promote the use of Celebrex for OA patients. As a result of such use, Celebrex became the standard course of treatment in such patients.

115. At the time these guidelines were written, the results of the CLASS study had not yet been published (the two articles were published almost simultaneously in September of 2000), but Defendants were aware of the results of the CLASS study. When the results of the CLASS study were published in JAMA, showing that Celebrex does not significantly reduce the risk of serious GI complications in comparison to other NSAIDs, Defendants did not seek to correct the guidelines, and continued to distribute reprints despite the fact that the guidelines did not reflect the best available scientific evidence. The authors, being paid by the pharmaceutical industry, did not print a correction and these guidelines continued to be used by physicians as the prescribing standard.

116. The guidelines ***may*** have been formulated on the best evidence that had been published at the time they were issued in the September 2000 issue of ARTHRITIS & RHEUMATISM.

But the CLASS study had been completed by March 2000 – and certainly this information ***should have been included*** in the guidelines that were issued in September 2000 and remained in effect through the time that Vioxx was taken off the market. These guidelines were available continuously on the government sponsored guidelines website, www.guideline.gov, during that time. There was no revision of the posted guidelines when the results of the CLASS studies were (such as they were) published in JAMA the same month, September 2000. The CLASS studies showed that among the subset of patients taking aspirin, those treated with Celebrex experienced no fewer GI complications than those treated with older, less expensive NSAIDs – even for the first six months of the study that were published. Nor were the guidelines updated when the FDA "Warning Letter" dispelled the claim that Celebrex is safer than other NSAIDs in patients on anti-coagulants. Nor were they updated with the data from the February 2001 Advisory Committee Meeting became available to the public on the FDA's website.

117. The guidelines listed factors that increase the risk of GI bleeding, and said that COX-2 inhibitors (Celebrex and Vioxx at the time) were the drugs of choice (after acetaminophen) for people at elevated risk. Even though the FDA reviewers dispelled that argument at the February 2001 Advisory Committee Meeting, the guidelines remained in place, not reflecting the updated information that should have caused them to be revised. Furthermore, in a section of the guidelines labeled "Initiation of treatment in the patient who is not at increased risk for an upper GI adverse event**,"** the guidelines state:

> The approach recommended for treatment of patients not at increased risk for an upper GI adverse event is similar to that described above (Table 3) [for people at increased risk]

In other words, for patients at increased risk and for those not at increased risk of GI complications, the guidelines recommend treatment with a COX-2 selective inhibitor if acetaminophen does not provide adequate relief – even though the FDA GI reviewer concluded that Celebrex offers a safety advantage for neither group. These guidelines set the standards of good medicine and are admissible in malpractice cases as evidence of community standards.

118. Another example of the use of manipulated studies to promote Celebrex use arises from publication of the article *The Coxibs, Selective Inhibitors of Clyclooxygenase-2* that appeared

in the NEW ENGLAND JOURNAL OF MEDICINE, Vol. 345, No. 6, on August 9, 2001. Though prohibited by the then editorial policy of the New England Journal of Medicine, both of the authors received money from Searle and/or Pharmacia. The authors concluded that, "clinical trials have demonstrated that treatment with highly selective cyclooxygenase-2 inhibitors [Celebrex and Vioxx] causes significantly fewer serious gastrointestinal adverse events than does treatment with non-selective NSAIDs." However, with the results of CLASS publicly available on the FDA website for seven months at the time this review article was published, the authors and Defendants were (or should have been) aware that there was no evidence of Celebrex being less likely to cause serious GI complications than other NSAIDs. Despite the error in this report, reprints of it were used by Defendants' sales force to market Celebrex to doctors.

119. Another example of the use of manipulated study data to promote Celebrex use is contained in a corporate-sponsored review article appearing in the BRITISH MEDICAL JOURNAL on September 21, 2002, where one of the authors was employed by Pfizer, which promoted falsely the

> In this review of randomised controlled trials we have shown that celecoxib is as effective as other NSAIDs for the relief from symptoms of osteoarthritis and rheumatoid arthritis. The confidence intervals around the point estimates of efficacy were reasonably narrow, which mean that it is unlikely that there were clinically important differences. Compared with other NSAIDs, however, celecoxib showed increased upper gastrointestinal safety and tolerability. Rates of withdrawal due to gastrointestinal adverse event, dyspepsia, and abdominal pain were 40-60% lower, while the incidence of ulcers and serious upper gastrointestinal events was 40-75% lower.

120. This review was published 2-1/2 years after the CLASS study was completed, and Defendants were aware that CLASS did not support this conclusion, yet Defendants took no corrective steps with respect to publication of this article.

121. Defendants even attempted to convince doctors that Celebrex was cardioprotective, with only a shred of inconclusive evidence and a wealth of scientific data to the contrary. In 2003, Defendants disseminated to health care professionals a small study that purported to demonstrate that "***celecoxib could not only be cardio-neutral, but may even be cardio-protective***." Defendants used the inconclusive study as a basis to promote Celebrex "as a unique agent with cardioprotective properties." ***Such promotion was contrary to Celebrex's FDA approved label***

that expressly warned that "CELEBREX is not a substitute for aspirin for cardiovascular prophylaxis" and falsely touted Celebrex as cardioprotective. Such promotion increased the sale of Celebrex by falsely inflating its image as having a superior CV safety profile over alternative NSAIDs. Even after the FDA required a black box warning on the Celebrex label warning of CV toxicity, Defendants did nothing to correct the false information they had disseminated regarding cardioprotection.

F. Defendants Provide Doctors With Misleading Literature

122. Prior to the publication of CLASS, Defendants continuously sent doctors materials that were false and misleading in order to create and expand the Celebrex markets. For example, in 1999, Defendants Searle and Pfizer co-promoted a series of slides used by the sales force, claiming that traditional NSAIDs resulted in $500 million in excess medical care costs for GI diseases. The implication intended was that Celebrex did not cause GI diseases. There was no scientific basis for such a claim and CLASS demonstrated otherwise, yet these claims stayed alive in the minds of physicians and helped promote Celebrex sales. And the FDA prohibited Defendants from even suggesting such a claim. This claim was never retracted or corrected by Defendants.

123. In 1999, Defendants sent literature to the medical community claiming that Celebrex demonstrated "significantly fewer GI ulcers in 12-week serial endoscopy studies." After CLASS was published, Defendants never corrected the misleading impressions created by this type of statement. And, such claims were forbidden by the FDA. In fact, in 2001, the FDA required pharmacies to send a corrective letter to doctors noting that Celebrex can cause "serious gastrointestinal toxicity."

124. At panel presentations to doctors on Celebrex, Defendants presented statistics showing costs arising from NSAID-associated GI diseases, juxtaposed against claims regarding "new Celebrex" and its effectiveness. This juxtaposition was designed to falsely convey the GI safety and cost/effectiveness of Celebrex. Also included were slides stating Celebrex "safely" delivers relief, again intending to create the false impression the older, less expensive NSAIDs were not as safe.

125. In a January 2000 letter to thousands of "Healthcare Professionals," jointly authored by Searle and Pfizer, Defendants described Celebrex as the "#1 selling brand of prescription arthritis medicine" and noted that "serious GI toxicity can occur with … NSAIDs." The message, no such GI toxicity occurs with Celebrex, this claim was unsupported and its falsity was never corrected and is contrary to the FDA's position on the safety of Celebrex.

126. In 2000, Pfizer and Searle sent doctors a description of Celebrex indicating that it has "excellent GI tolerability." Again, this was part of a successful effort to create the impression that Celebrex caused significantly fewer GI problems than the older, less expensive NSAID. This statement was misleading when made and never corrected.

127. In 2000, Defendants jointly agreed to send doctors materials describing Celebrex as a "scientific breakthough" which was not the case. Celebrex has no "breakthrough" clinical advantage over the older, less expensive NSAIDs, and the FDA prohibited such comparative claims of superiority.

128. In 2000, Defendants jointly agreed to send doctors materials claiming that Celebrex was more effective in pain relief than naproxen. This claim was based on a study published in 1999 [Pharmacotherapy 19(11):1269-78, 1999], in which the primary endpoint was functional status and Celebrex and naproxen were equivalent. The finding that Celebrex reduced pain more than naproxen was post-hoc, and therefore of far less importance. The FDA Medical Officer Review commented on the results of CLASS:

> While these protocols were not primarily intended to address effectiveness, it is disappointing that celecoxib at four times and twice the upper recommended dose for OA and RA, respectively, appeared to offer no substantial therapeutic gains.

129. All of the above materials are just examples of false and misleading materials that conveyed superiority claims that persist in the medical community and led to the astounding success of Celebrex. These materials were used by the Pfizer sales force to convince doctors and Third-Party Payors of Celebrex's superiority.

G. Direct to Consumer Marketing and Promotion

130. With the knowledge that Celebrex provides no better pain relief than older anti-inflammatory drugs (in fact, all doses of Celebrex provide significantly less relief in studies of dental pain than two over the counter Advil tablets) and that Celebrex is no less likely to cause serious GI complications, Defendants continued pouring money into advertising campaigns that uniformly emphasized the GI and CV safety of Celebrex and its relief of symptoms.

131. Pharmacia and Searle spent more than $78 million on consumer advertising for Celebrex just in the year 2000. Defendants spent more than $400 million on direct-to-consumer advertising for Celebrex from 1999 to 2003. Defendants' direct-to-consumer advertising had as its goal convincing patients that Celebrex was clinically superior to older, less expensive NSAIDs and that they should see their doctors and request a prescription for Celebrex. This was accomplished by use of the messages set forth below.

132. In addition, Defendants' sales forces have blitzed doctors' offices with literature and verbal presentations designed to convince both doctors and consumers that Celebrex was a superior drug for treatment of osteoarthritis, acute pain in adults, painful menstrual cycles and other types of disease. They aggressively promoted Celebrex as an improvement over other NSAIDs, like naproxen and ibuprofen, because it had a lower risk of side effects such as GI ulcers and bleeding and had a safe CV profile. Defendants did not promote a fair and balanced presentation of Celebrex and promoted Celebrex in a manner inconsistent with FDA approval and Celebrex's labeling.

133. Such marketing efforts to physicians have become commonplace in recent years. Drugs, including Celebrex, that might once have been used primarily by specialists are routinely promoted to, and prescribed by, doctors who are less familiar with the drugs' full research record. Drug companies, with Pfizer in the forefront, spent billions on such "detailing" to physicians – *i.e.*, sales people dropping by to leave marketing materials and drug samples, and speaking to physicians about their companies' drugs.

134. Such large-scale marketing efforts have paid huge dividends to Defendants and other drug companies. The number of blockbuster drugs, defined as drugs with more that $1 billion in annual retail prescription sales, was only 15 in 1999 but grew to 34 in 2003.

135. As a result of Defendants' uniformly misleading advertising campaigns, Celebrex was wildly successful. Celebrex became Pharmacia's best selling drug with more than $2.6 billion in sales for 2000 and $3.1 billion in sales for 2001. After acquiring Pharmacia, Pfizer has continued to enjoy blockbuster sales of Celebrex, with $2.7 billion in revenue from U.S. sales (out of $3.3 billion in worldwide sales) in 2004.

H. Examples of Misleading Materials Designed to Promote Celebrex as Offering a Heretofore Unavailable Improvement in the Quality of Life and/or as Providing Superior Pain Relief

136. Despite the lack of scientific evidence to support such claims, Defendants' advertisements often focused on one of two themes that were either expressly stated or implied by the words and images. One was that Celebrex provided previously unavailable improvements in quality of life. The second was that Celebrex provided superior pain relief.

137. The marketing plans for Celebrex were not impeded by the FDA approval requiring a GI warning. The marketing plan went forward in large measure with a concerted effort to disguise the true scientific evidence about the safety and efficacy of Celebrex.

138. From 1997 through the present, Defendants have repeatedly engaged in misleading advertising devised to portray Celebrex as safer than other pain relievers.

139. For example, on January 29, 1999, the FDA sent Defendant Searle comments on the proposed launch marketing materials for Celebrex. The comments included criticism of the Defendants' presentation of the COX-1 and COX-2 science, stating that such presentations,

> suggest that by selectively inhibiting COX-2, Celebrex™ does not cause the typical adverse effects on the gastrointestinal (GI) tract and platelets observed in the class of NSAIDs. This broad superiority claim comparing Celebrex™ to the class of NSAIDs is misleading because it is based on nonclinical data and is not supported by evidence found in the approved product label.

140. The FDA further rejected any "suggestion" by graphics or through words that Celebrex has a universally superior clinical safety profile to NSAIDs as a class since such a claim

had not been proven and was contradicted Celebrex's labeling that "[i]n fact, [includes] much of the class labeling for NSAIDs with regard to safety."

141. Among multiple other concerns regarding Defendant's marketing, the FDA highlights the Defendants selective promotion of safety data at the expense of important risk information. The FDA specifically criticizes Defendant's presentation of the "Hepatic and Renal Safety Profile," in a Celebrex advertisement as follows,

> The heading "Hepatic and Renal Safety Profile" appears at the top of page 11. The information contained on this page presents several promotional claims for Celebrex™ but omits risk information contained in the PRECAUTIONS section of the product label under the subheadings Hepatic Effects and Renal Effects. For example, the product label contains the statements "Rare cases of severe hepatic reactions, including jaundice and fatal fluminant hepatitis, liver necrosis and hepatic failure (some with fatal outcome) have been reported with NSAIDs" and "Long term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury." However, none of this important safety information appears on this page. These statements would be considered false or misleading because the presentation of information under the title "Hepatic and Renal Safety Profile" that does not include relevant renal or hepatic precautions form the approved label is a presentation that otherwise selects information in a way that makes the drug appear to be safer than has been demonstrated.

Another concern addressed by the FDA, is the Defendants' failure to present a fair balance of Celebrex's general safety by omitting information regarding GI risks and failing to mention "significant information in the PRECAUTIONS section. For example, there is no information regarding renal or hepatic effects."

142. Again on March 12, 1999, the FDA criticizes the Defendants Celebrex marketing as overstating efficacy, misleading regarding GI risks, failing to accurately present comparative claims and overstating the general safety. Regarding the Defendants' portrayal of the general safety of Celebrex the FDA comments,

> The audio in frame 18 states that Celebrex is "generally well tolerated." This appears in the ad before the presentation of any risk information including adverse reactions, warnings and contraindications. The term "generally well tolerated" minimizes the significance of the risk information that follows. Therefore DDMAC suggests that Searle delete this term. The ad also fails to state several other important risks associated with the use of Celebrex. Cautionary language regarding the risk to asthmatics and patients with renal disease should also be present in the add.

143. On October 6, 1999, the FDA sent Defendant Searle another letter regarding misleading claims with respect to Celebrex. The FDA found as follows:

> NDA #20-998
>
> - Searle claims that, "With more than 5 million patients on Celebrex, physicians know what to expect when they prescribe Celebrex – the new standard of care for analgesic and anti-inflammatory therapy in the management of pain for OA and RA." This statement makes a broad superiority claim comparing Celebrex to not only the class of NSAIDs, of which Celebrex is a member, but to all analgesic and anti-inflammatory therapies available for the management of osteoarthritis (OA) and rheumatoid arthritis (RA). However, this global superiority claim has not been demonstrated by substantial evidence. Therefore, this claim is false or misleading.
>
> - Searle also presents several unsubstantiated comparative claims to Vioxx (rofecoxib), including but not limited to, "Why should I use Celebrex over Vioxx? My first response to your question leads me to ask, 'With all the experience that you and thousands of other physicians just like you have with the proven efficacy and ***benefit of superior safety of Celebrex***, why wouldn't you want to prescribe Celebrex?'" (emphasis added). This claim suggests Celebrex has a "superior safety" profile compared to Vioxx, when such has not been demonstrated by substantial evidence. Therefore, DDMAC considers this unsubstantiated comparative claim to be false or misleading.

144. Typical of Defendants' misleading advertising is an advertisement called "Guitar TV ad." The Guitar TV advertisement in its entirety makes a representation about the indication and benefits of Celebrex for osteoarthritis or rheumatoid arthritis. A woman playing an acoustic guitar is featured. The visuals focus on her hands/fingers and playing ability (*i.e.*, she finger-picks the strings with one hand while executing chord changes with the other hand). These images are accompanied by a voice-over: "With Celebrex, I will play the long version." Together, these images and claims suggest that because of using Celebrex, there is a direct benefit to this patient's wrist/hand/finger joints related to movement and flexibility such that she can now play the long version of the song whereas she previously could not.

145. This advertisement is just one of many designed to have consumers believe that Celebrex will provide better relief or in some way improve the quality of their lives more than older, less expensive NSAIDs, many of which are available without a prescription.

146. Recently, the FDA issued a warning letter regarding this advertisement:

> While the Guitar TV ad suggests a direct benefit to this patient's wrist/hand/finger joints related to movement and flexibility, it fails to state the actual approved indication (*e.g.*, relief of signs and symptoms of osteoarthritis). It also fails to include any risk information about Celebrex, thus omitting the major side effects and contraindications (including warnings and precautions) of Celebrex as required by 21 CFR 202.1(e)(1). Omission of this information implies that there are no risks to the patient who takes Celebrex, which overstates the drug's safety.

147. Similarly the FDA found another Celebrex TV advertisement to be misleading. The FDA described this advertisement as follows:

> *Announcer: "Celebrex presents, arthritis tips."*
>
> Woman dressed as doctor: "Arthritis is the most wide-spread crippling disability in the United States today. Arthritis is the predominant cause of activity limitations and is a major determinate of nursing home institutionalization for the elderly. One out of every 7 people and 1 in every 3 families is affected by arthritis. If you feel any pain or discomfort in your joints, contact your local doc."
>
> *Announcer: "These arthritis tips have been brought to you by Celebrex."*

148. The FDA found this advertisement to be misleading.

> The Arthritis Tips TV ad is a product-specific drug ad for Celebrex that is misleading because it omits important information about the drug's safety and effectiveness and makes unsubstantiated effectiveness claims. The ad promotes Celebrex by identifying the drug by name at the beginning and end of the ad. Moreover, stating that Celebrex is presenting/bringing you arthritis tips clearly suggests that Celebrex is an arthritis treatment. The Arthritis Tips TV ad purports to quantify the disease burden of "arthritis" ("the most wide-spread crippling disability in the United States today … the most predominant cause of activity limitations and … a major determinate of nursing home institutionalization for the elderly. One out of every 7 people and 1 in every 3 families is affected by arthritis.") Finally, the Arthritis Tips TV ad directs viewers to contact their local doctor "if you feel any pain or discomfort in your joints" and follows this statement with another reference to Celebrex.
>
> <u>Overstatement of Effectiveness</u>. The Arthritis Tips TV ad is misleading because it overstates the proven effectiveness of Celebrex for the treatment of "arthritis." The Arthritis Tips TV ad discusses the serious progressive effects of arthritis, noting that it commonly can lead to "crippling disability" and "nursing home institutionalization of the elderly." The viewer is then instructed "if you feel any pain or discomfort in your joints, contact your local doc. These arthritis tips have been brought to you by Celebrex." The totality of this presentation therefore suggests that Celebrex is an

> effective treatment for preventing or modifying the progression of arthritis, such that crippling disability and nursing home institutionalization may be avoided.
>
> Celebrex is indicated only for relief of the signs and symptoms of OA and RA. Celebrex is not indicated for disease modification (i.e., altering the course of the progression of arthritis). Moreover, we are not aware of substantial evidence or substantial clinical experience demonstrating that treatment with Celebrex will prevent crippling effects or disability due to arthritis or prevent nursing home institutionalization of elderly patients with arthritis. Therefore, your Arthritis Tips TV ad greatly overstates the proven benefits of Celebrex.
>
> Omission of Risk Information. The Arthritis Tips TV ad fails to disclose any risk information about Celebrex and thus omits the major side effects and contraindications (including warnings and precautions) of Celebrex as required by 21 C.F.R. 202.1(e)(1). Omission of this information implies that there are no risks to the patient who takes Celebrex, thus overstating its safety.

149. In the same letter the FDA found that various Celebrex print advertisements made unsubstantiated claims with respect to less expensive alternative drugs:

> Unsubstantiated Superiority Claims
>
> The print ad features the prominent headline "Strength They Can Stay With" and shows a chart comparing Celebrex, Ibuprofen and Naproxen, titled "6-Month Patient Persistency Rate." Over the chart is the statement, "In a study of approximately 1 million patients, persistency rates of different OA/RA treatments were assessed at 6 months." The tagline below the Celebrex logo in the print ad is "Proven strength that lasts."
>
> The above referenced claims imply that Celebrex is more effective (i.e., stronger) than ibuprofen and naproxen for treatment of osteoarthritis or rheumatoid arthritis and that patients "stay with" or are more compliant with Celebrex therapy than the compared products. We are not aware of substantial evidence or substantial clinical experience to support these claims. The cited retrospective retail pharmacy database analyses by NDC Health, "Persistency Analysis: Celebrex, Vioxx, and All Other NSAIDs," August 2002 and "Persistency Analysis: Celebrex, Vioxx, Ibuprofen, and Naproxen," from November 2002 (almost 2 years ago), do not contain any data or information demonstrating that patients found Celebrex to be more effective than the other products, or that patients will be more "persistent" or compliant with Celebrex therapy. Moreover, the database information did not note the indication for which the drug was prescribed, so the suggestion that these rates reflect specifically OA/RA patients is misleading. In addition, the analyses do not account for factors that affect persistence or compliance such as cost insurance coverage, side effects, dosage regimen, and ease of use. Therefore, the analyses do not constitute substantial evidence or substantial clinical experience demonstrating

> that OA/RA patients are more compliant with Celebrex or stay on Celebrex longer because it is more effective than other products for the treatment of OA or RA.

150. Since its introduction, Defendants have issued promotional material designed to tie Celebrex to improving quality of life. It has distributed materials making numerous dramatic claims tied to the drug regarding quality of life, in terms of being able to do personal and work-related activities. A Pfizer infomercial shows people returning to their work and activities. These patients go from not being able to work or do anything they want to do, to being able to work and do everything they want to do, pain-free. Patients talk about being able to "do anything," "do as much as I want to do," being "back to doing what I do," and such. They talk about "enjoying life" again, how the drug improved their "quality of life," and how the drug "gave them back their lives" (a theme repeated over and over in the advertisement and in the background music). One person states that "you can be free." Another states that the medicine "brought new vitality in life." Everyone portrayed has 100% efficacy in all of these outcomes.

151. Such claims are misleading and purport to promote Celebrex as superior. In fact, as the FDA has recently noted, "none of the comparative studies with naproxen, ibuprofen, and diclofenac to-date has been designed to demonstrate superiority or a specified degree of similarity in a rigorous way."

152. In addition, Defendants designed, approved and caused to be published the following advertisements which were designed to appeal to consumers or doctors which misstated or deceptively conveyed Celebrex's superiority.

153. TELEVISION ADVERTISEMENT: ***The "I Will Not" advertisement***. This campaign, ran in October 2003 and April 2004, portrays people engaging in various physical activities. The tag line for the advertisement is "With Celebrex I will not …" This is followed by various variations in this theme.

a. The advertisement shows a woman jogging with announcer stating: "With Celebrex I will no longer give in to the joint pain of osteoarthritis. Just one Celebrex provides up to 24 hour relief from the pain of osteoarthritis."

b. The advertisement shows a woman playing golf with announcer stating: "With Celebrex I will not stop at 9 when I really want to play 18." The announcer further states: With Celebrex I will not settle for part time relief. If you are struggling with joint pain maybe you should stop trying to manage it by yourself."

c. The advertisement shows a woman running on a beach, a woman playing golf, people doing tai chi, a man pitching softball, a couple hiking, a man pushing a child on a marry-go-round, a man swimming and a woman kayaking. The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says, "Individual results may vary."

154. Each of the "I Will Not" foregoing advertisement scenes overstate the effectiveness of Celebrex. Each implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. And each misrepresents the fact that the relief provided by Celebrex is not superior to that provided by older, less expensive NSAIDs, several of which are available without a doctor's prescription. The small disclaimer regarding individual results does not effectively counter or balance the overall intended message of this advertisement.

155. The "I Will Not" advertisement makes unsubstantiated superiority claims. By stating that "if you are struggling with joint pain maybe you should stop trying to manage it by yourself" the advertisement falsely implies that Celebrex is superior to over-the-counter NSAIDs, and created unnecessary physician visits by conveying the message a doctor can prescribe a medication that is superior to those available without a prescription.

156. TELEVISION ADVERTISEMENT: ***The "Fixing the Preschool" advertisement***. The theme of this campaign, which ran during May 2001, is a group of people fixing up a building that will be a preschool. The advertisement starts out with the voice-over: "If you have osteoarthritis there is reason to celebrate … Celebrex." The advertisement then shows people engaging in various activities repairing the schoolhouse. It shows a man on a ladder taking down a sign with the text: "Mark, arthritic shoulder." It shows a woman cleaning a blackboard with the text: "Sarah, arthritic back." The announcer states, "Celebrex specifically targets only the Cox-2

enzyme – a key source of arthritis pain. Celebrex relieves arthritis pain plus stiffness too." The advertisement shows a woman working with a trowel, with the text: "Julia, arthritic hands." The announcer states: "Powerful 24 hour relief from osteoarthritis pain, inflammation and stiffness." The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says "Individual results may vary."

157. This campaign overstates the effectiveness of Celebrex and implies complete pain relief and complete return of movement and functionality for all patients, which is not representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results does not correct, counteract or balance the overall message of this advertisement.

158. This advertisement campaign makes unsubstantiated superiority claims. By stating that "Celebrex specifically targets only the Cox-2 enzyme – a key source of arthritis pain" it falsely implies that Celebrex is superior to other NSAIDs.

159. TELEVISION ADVERTISEMENT: ***"The Softball Game" Advertisement***. The theme of this advertisement, run during September 2000 and May 2001, is a softball game. The advertisement starts out with the announcer stating: "If you have osteoarthritis there is reason to celebrate … Celebrex." The announcer states: "Celebrex specifically targets only the Cox-2 enzyme – a key source of arthritis pain. 24 hour relief from pain and stiffness." The ad shows a woman helping a young boy to bat, with the text: "Jill, arthritic hands." It shows a group of women doing the wave, with the text: "Rita, arthritic back." It shows the umpire raising his arms overhead, with the text: "John arthritic shoulder." The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says "Individual results may vary."

160. This advertisement overstates the effectiveness of Celebrex. It implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results does not correct, counteract or balance the overall message of this advertisement.

161. This advertisement makes unsubstantiated superiority claims. By stating that "Celebrex specifically targets only the Cox-2 enzyme – a key source of arthritis pain" it falsely implies that it is superior to other NSAIDs.

162. TELEVISION ADVERTISEMENT: ***"A Day in the Park" Advertisement.*** The theme of this advertisement, which ran during November 2000, is people engaging in various activities in a park. The advertisement starts with a theme song "celebrate, celebrate do what you like to do." The announcer states: "If you have osteoarthritis there is reason to celebrate it's Celebrex. Powerful 24 hour relief from osteoarthritis pain and stiffness. Celebrex is the first arthritis medicine that targets only the Cox-2 enzyme." The advertisement shows people doing tai chi, with the text: "Ann, arthritic shoulder." The ad shows a man and a child riding push scooters, with the text: "Bill, arthritic knee." It shows a man rowing a boat with the text: "Dave, arthritic shoulder." It shows a woman pushing a child on a swing with the text: "Liz, arthritic back." The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says "Individual results may vary."

163. This advertisement overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results does not correct, counteract or balance the overall message of this advertisement.

164. This advertisement makes unsubstantiated superiority claims. By stating: "Powerful 24 hour relief from osteoarthritis pain and stiffness. Celebrex is the first arthritis medicine that targets only the Cox-2 enzyme" the ad falsely implies that Celebrex is superior to other NSAIDs.

165. TELEVISION ADVERTISEMENT: ***"I Will Not …" Advertisement #2.*** The advertisement portrays people engaging in various physical activities. The tag line for the ad is: "With Celebrex I will not give in to the pain of osteoarthritis." The advertisement shows a man swimming, a couple canoeing and a woman running. The announcer states: "Just one Celebrex provides up to 24 hour relief from the pain of osteoarthritis." The ad shows a woman playing golf with a voice over: "With Celebrex I can line up my putt." It shows woman playing a guitar with the voice over: "I can play the long version." The announcer states: "One pill, 24 hours so you can live your life the way you want. With Celebrex I will not settle for part time relief." The

advertisement shows people hiking, a woman painting a chair, a man fishing, a woman playing a guitar, people doing yoga and a man pushing a merry-go-round. The announcer states, "If you are suffering from pain, inflammation or stiffness maybe you should stop trying to manage it on your own." The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says "Individual results may vary."

166. This advertisement overstates the effectiveness of Celebrex. It implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results does not correct, counteract or balance the overall intended message of this advertisement.

167. The advertisement makes unsubstantiated superiority claims. By stating that "if you are suffering from pain, inflammation or stiffness maybe you should stop trying to manage it on your own" the advertisement implies that it is superior to over-the-counter NSAIDs which is not supported in clinical trials. By stating, "with Celebrex I will not settle for part time relief" the advertisement implies that it is superior to other arthritis treatments which is not supported in clinical trials.

168. TELEVISION ADVERTISEMENT: ***"Dancing" Advertisement***. The theme of this advertisement, which ran during July 2002, is people dancing. The advertisement shows a couple dancing with a voice over that states: "Even with osteoarthritis these arms still have a way with the ladies." The text on screen says: "Arthritic Elbow." The next scene shows a woman dancing, with a voice over that states: "These legs hardly miss a beat" with text "arthritic knee." The next scene shows a couple dancing, with the voice over: "These hands haven't lost their touch" with text "arthritic hands." The announcer states: "Just one Celebrex last 24 hours. Provides powerful arthritis pain relief that is non-narcotic." The advertisement has additional footage of the above people dancing. The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says "Individual results may vary."

169. This advertisement overstates the effectiveness of Celebrex. It implies complete pain relief and complete return of movement and functionality for all patients which is not

representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results does not correct, counteract or balance the overall message of this advertisement.

170. Each of the foregoing advertisements, and Defendants' overall advertisings or marketing program for Celebrex, consistently and uniformly failed to disclose the increased risk of heart problems that were known to Defendants at the time Celebrex was launched. Defendants concealed a study completed June 24, 1999 comparing Celebrex to placebo for the slowing of the progression of Alzheimer's Disease and overall safety. Patients taking Celebrex were 3.6 times more likely to experience a serious cardiovascular event (2.1% of patients taking placebo vs. 7.7% of patients taking Celebrex).[6] Pfizer's report of this study shows that the increased risk of CV complications in patients taking Celebrex was statistically significant.[7] Furthermore, among patients taking Celebrex there were 12% more serious adverse events (25.6% vs. 22.9%) and 59% more deaths (4.6% vs. 2.9%). The study was never published and was not presented to the FDA in time to be included in the February 2001 Advisory Committee Meeting that considered the safety of Celebrex. Had the findings from this study been published and disclosed to the FDA in a timely manner, sales of Celebrex – based primarily on the claimed safety advantage over older, less expensive NSAIDs – would have been dramatically less. These findings would have been of singular importance to prescribing doctors given the concern, appropriately expressed in the JAMA article reporting the first six months of the CLASS study, about the theoretical risk of increased adverse events disturbing the clotting balance with selective COX-2 inhibition:

> Although it has been hypothesized that COX-2–specific inhibitors might increase the risk of cardiovascular thromboembolic events via inhibition of vascular prostacyclin synthesis without a corresponding inhibition of platelet thromboxane, no such increase was evident in the current study.

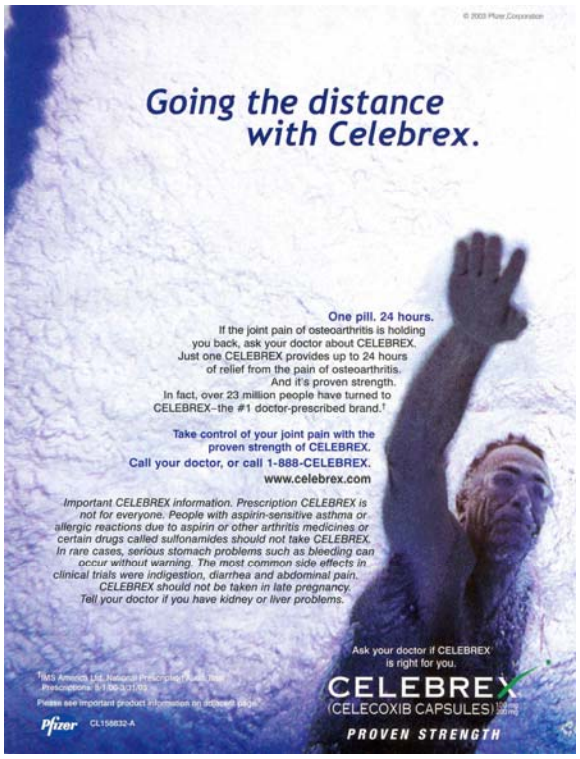
[6] Letter to FDA revealing heart dangers in an unpublished clinical trial of Celebrex (HRG Publication #1721), Public Citizen, January 31, 2005. http://citizen.org/publications/release.cfm?ID=7359.

[7] A statistically significant difference favoring placebo in adverse events was observed for certain CV-related body system terms (Cardiovascular Disorders, General; Heart Rate and Rhythm Disorders; Myo, Endo, Pericardial & Valve Disorders). These differences were primarily driven by the individual terms cardiac failure, fibrillation atrial, and angina pectoris. http://www.clinicalstudyresults.org/documents/company-study_76_0.pdf.

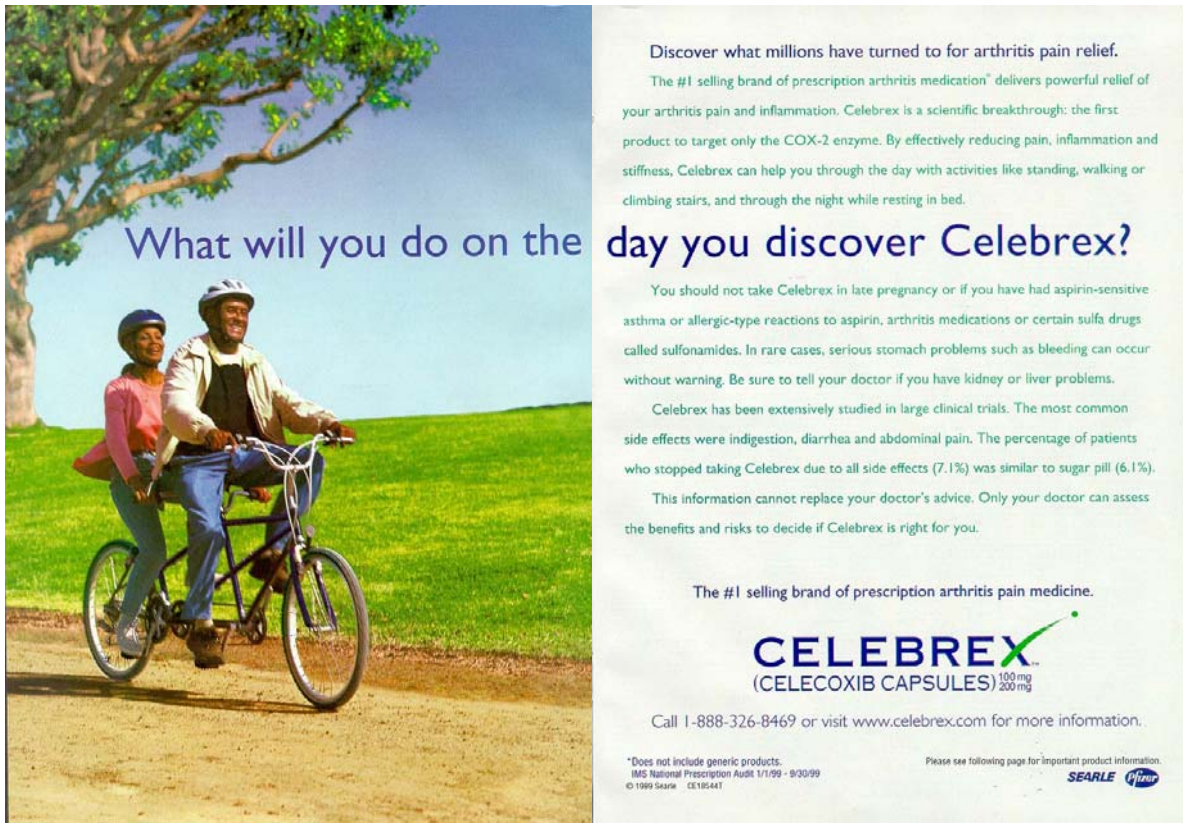
Defendants' failure to make the results of this study available are particularly vexing, because it was completed eight months before the CLASS study was completed, and it's results should have informed the report published in JAMA.

171. Despite Defendants' knowledge of increased CV risk with Celebrex, Defendants promoted it as having CV benefits.

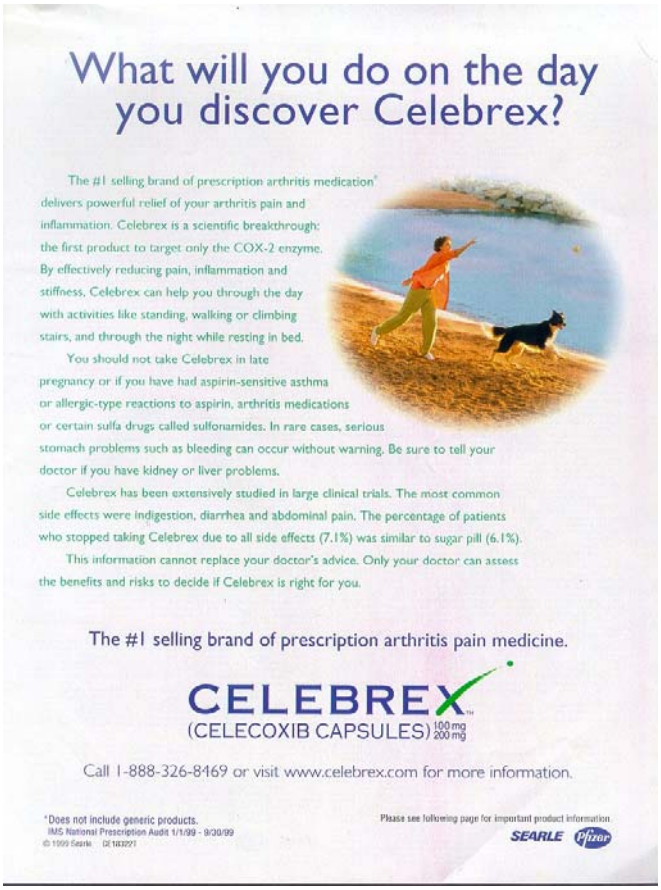
172. As part of the scheme alleged herein, Defendants engaged in a massive direct-to-consumer advertising campaign in the print media designed to create consumer demand for Celebrex. The following is a sampling of such advertisements.



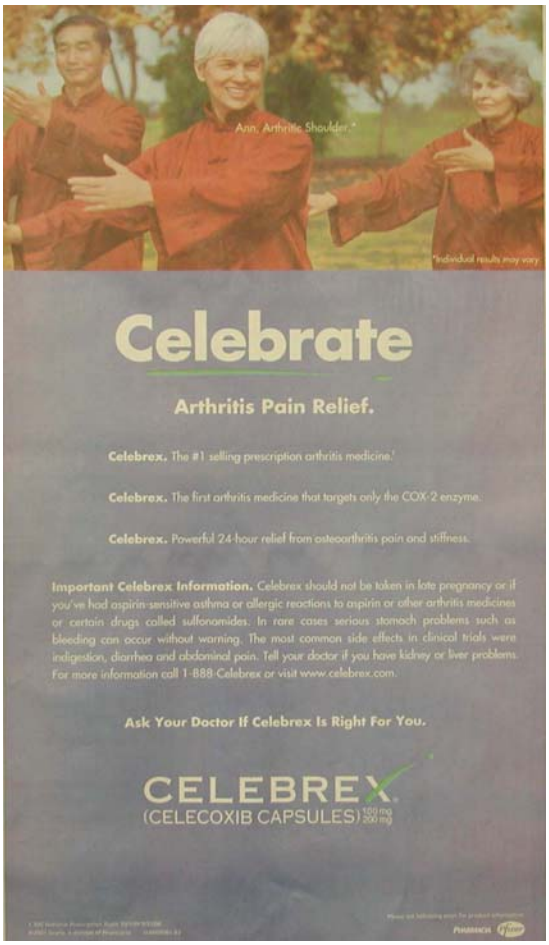
173. This advertisement, which ran during October 2003, overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. It also seeks to bolster its image and acceptance by claiming that 23 million people are using it and by virtue of the fact it is the "#1 doctor-prescribed drug." However, these figures, if true, are misleading by virtue of acceptance of Celebrex was the result in large measure to Defendants' deceptive scheme for marketing Celebrex.



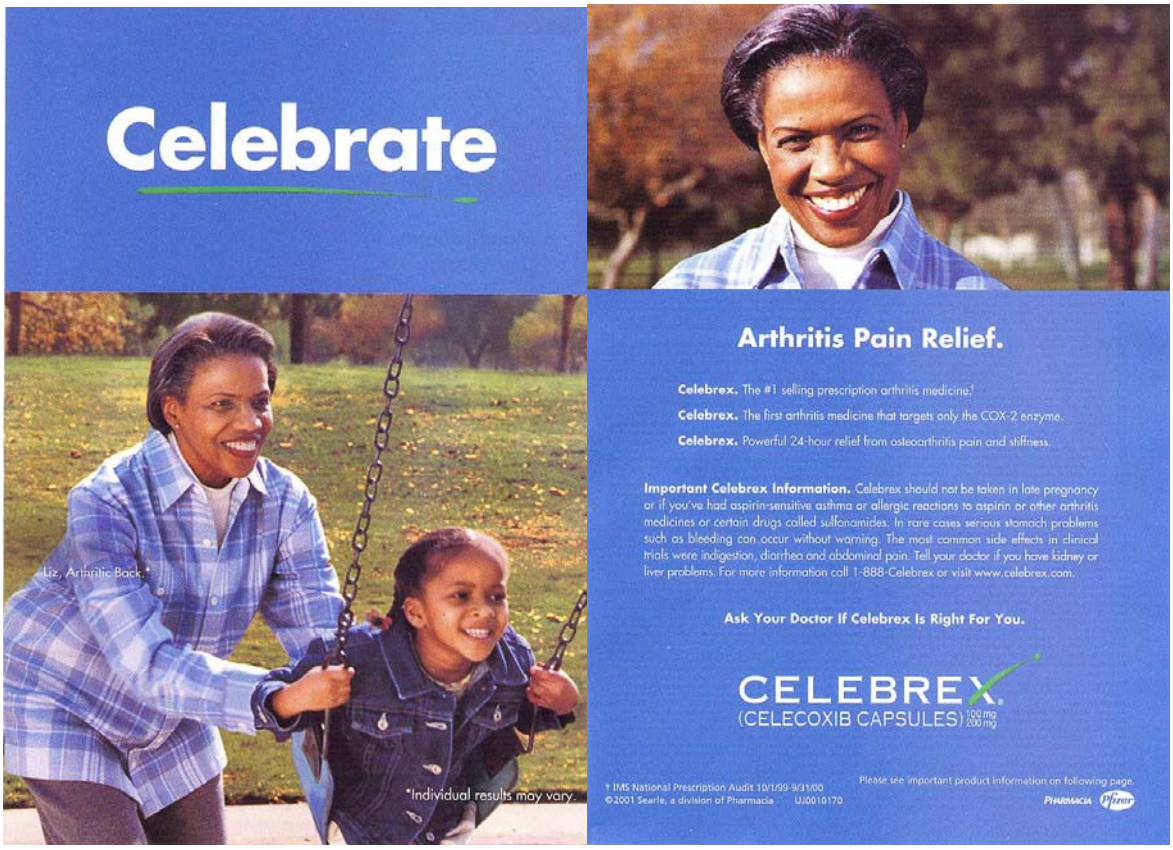
174. This advertisement, which ran during January 2000, overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. The advertisement claims that Celebrex is a "breakthrough" implying that it is superior to other NSAIDs, a claim which is not supported in clinical trials, and in fact is misleading, given the lack of statistical significance between Celebrex and older NSAIDs, and the lack of disclosure of the cardiovascular risks presented by Celebrex. It also represents that it is the "#1 selling brand" which would not have been the case if Defendants had not engaged in the unlawful scheme described herein.



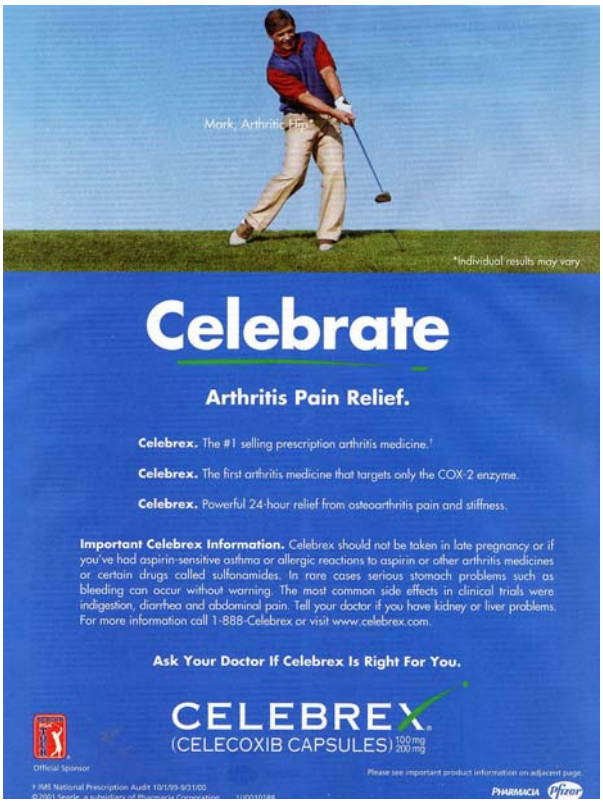
175. This advertisement, which ran during March 2000, overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims without disclosure of cardiovascular risks. The advertisement claims that Celebrex is a "breakthrough" implying that it is superior to other NSAIDs which is not supported in clinical trials.



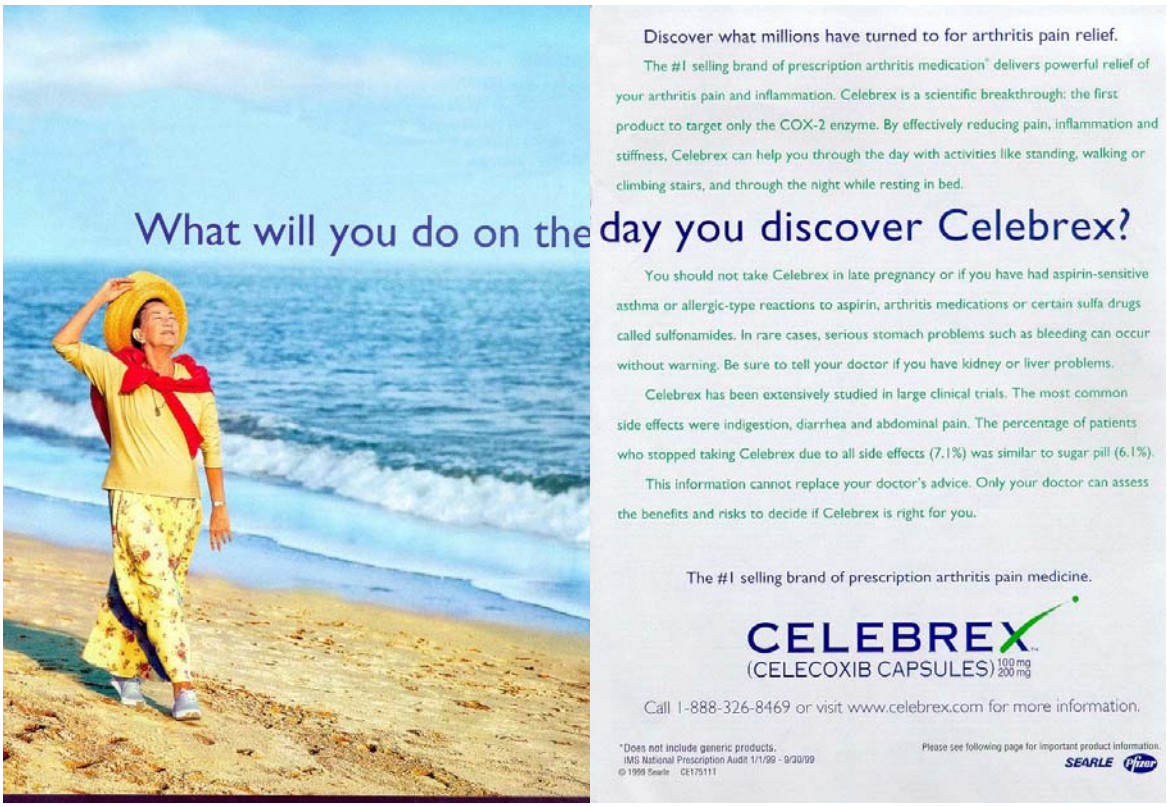
176. This advertisement, which ran during January 2001, overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. By stating that it is the "first arthritis medicine that targets only the COX-2 enzyme" it wrongly implies that it is superior to other NSAIDs and fails to disclose the cardiovascular risks associated with Celebrex, thus implying it is cardiovascularly safe.



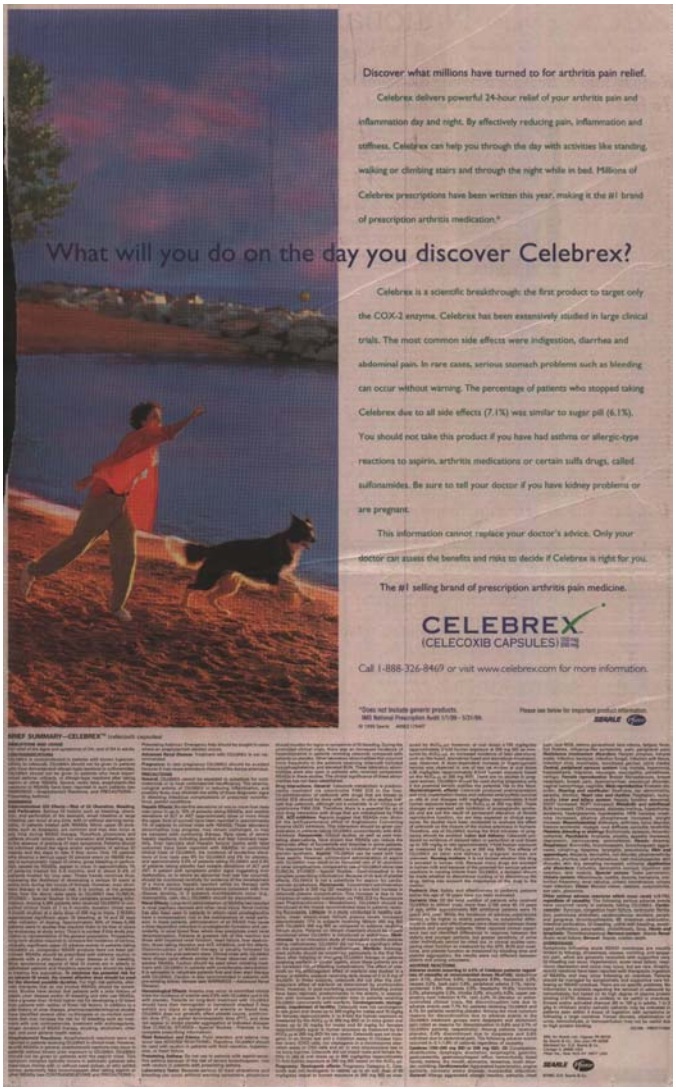
177. This advertisement, which ran during June 2001, overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims and fails to disclose the cardiovascular risks associated with Celebrex. By stating that it is the "first arthritis medicine that targets only the COX-2 enzyme" it falsely implies that it is superior to other NSAIDs.



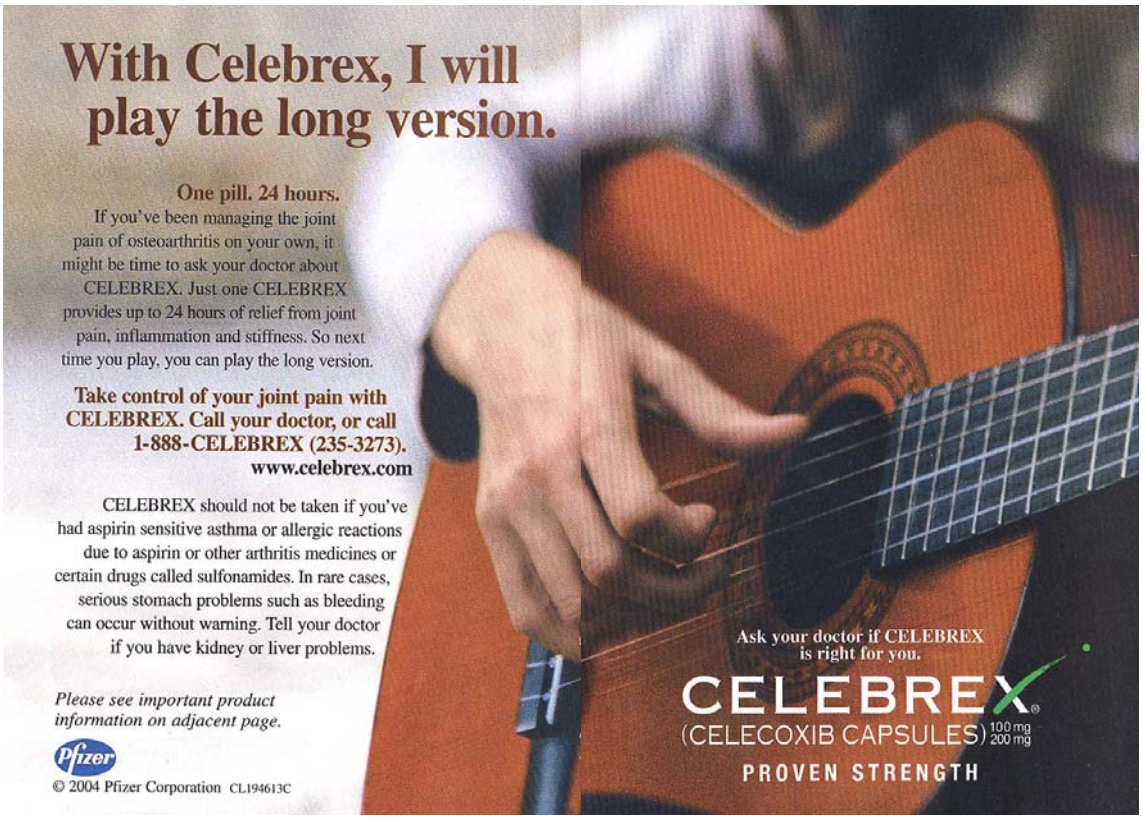
178. This advertisement, which ran during May 2001, overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims without disclosure of the cardiovascular risks associated with Celebrex. By stating that it is the "first arthritis medicine that targets only the COX-2 enzyme" it falsely implies that it is superior to other NSAIDs.



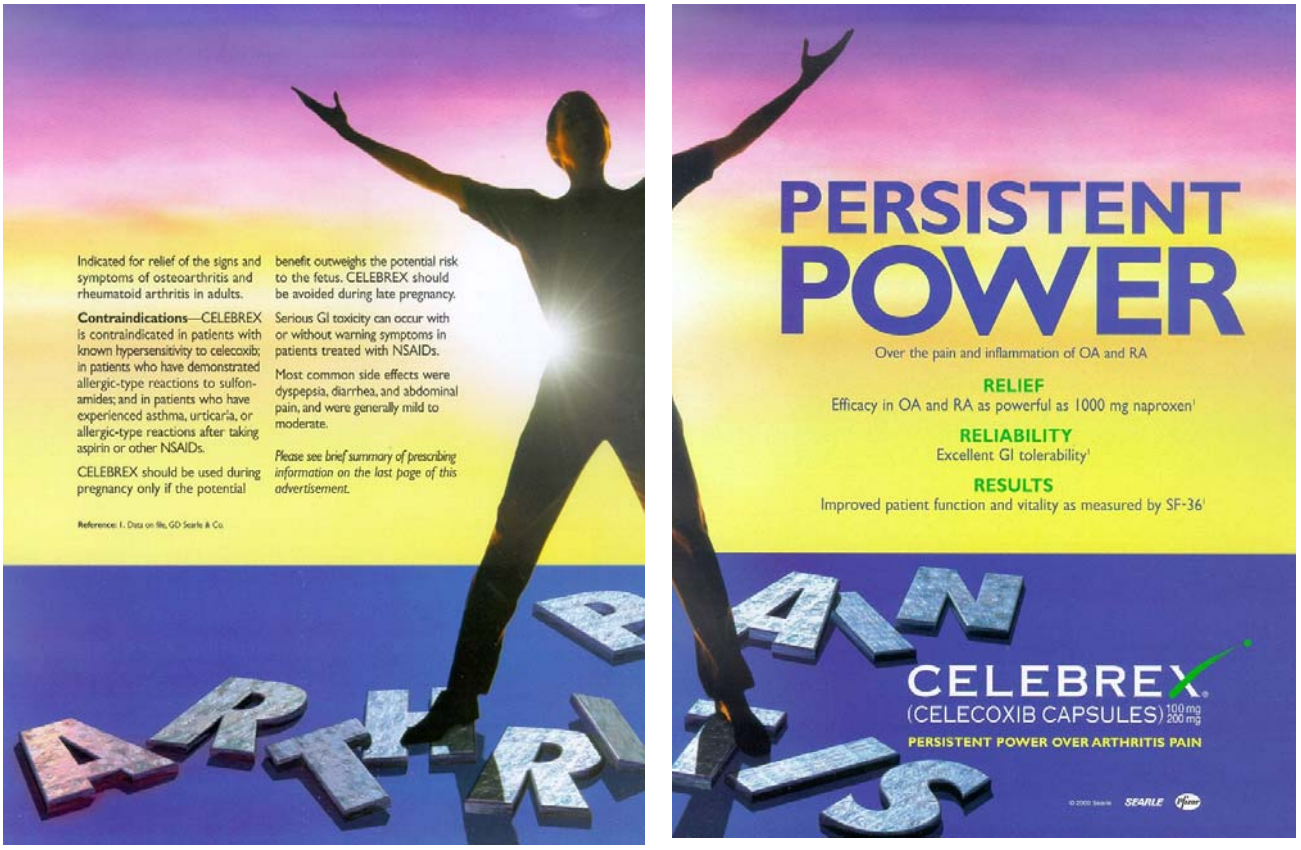
179. This advertisement, which ran during February 2000, overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims and implies cardiovascular safety by not including the cardiovascular risks. The advertisement claims that Celebrex is a "breakthrough" falsely implying that it is superior to other NSAIDs.



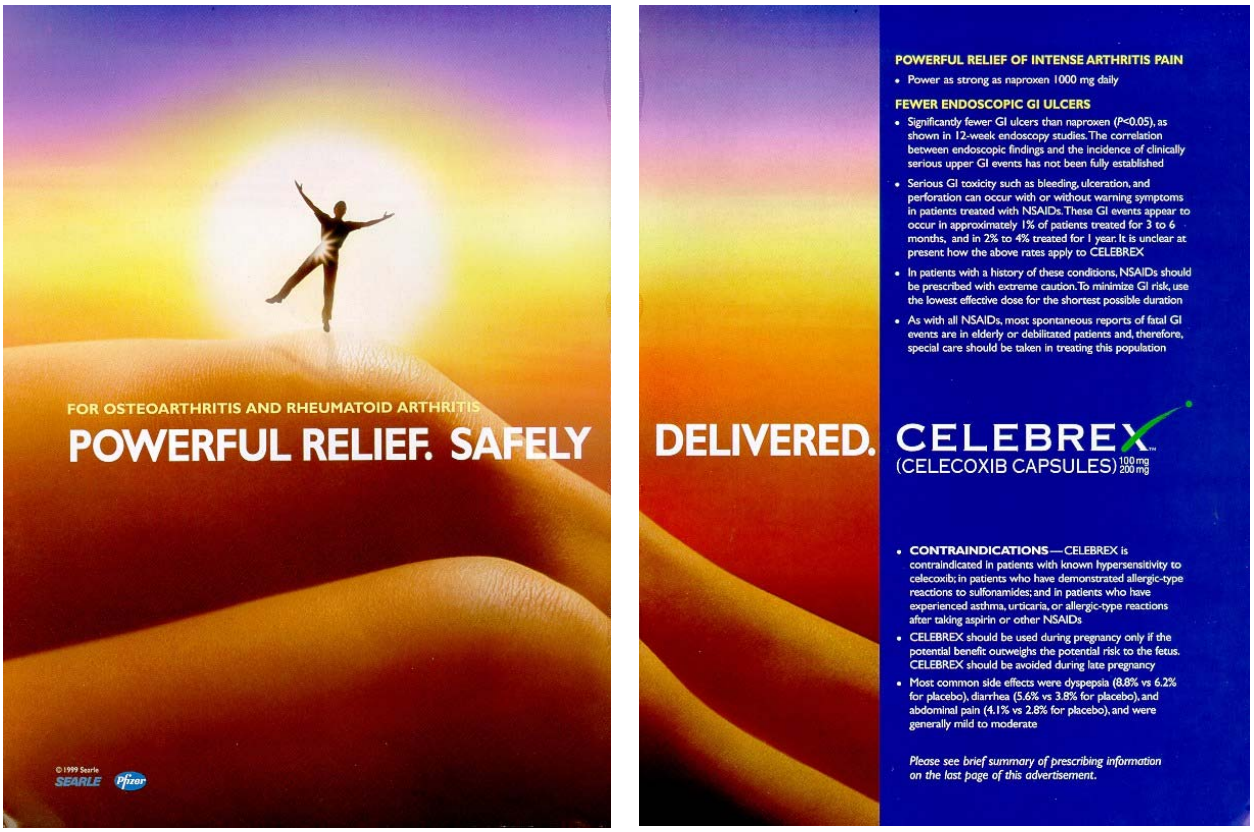
180. This advertisement, which ran during September 1999, overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims and implies that Celebrex is safe cardiovascularly. The advertisement claims that Celebrex is a "breakthrough" falsely implying that it is superior to other NSAIDs.



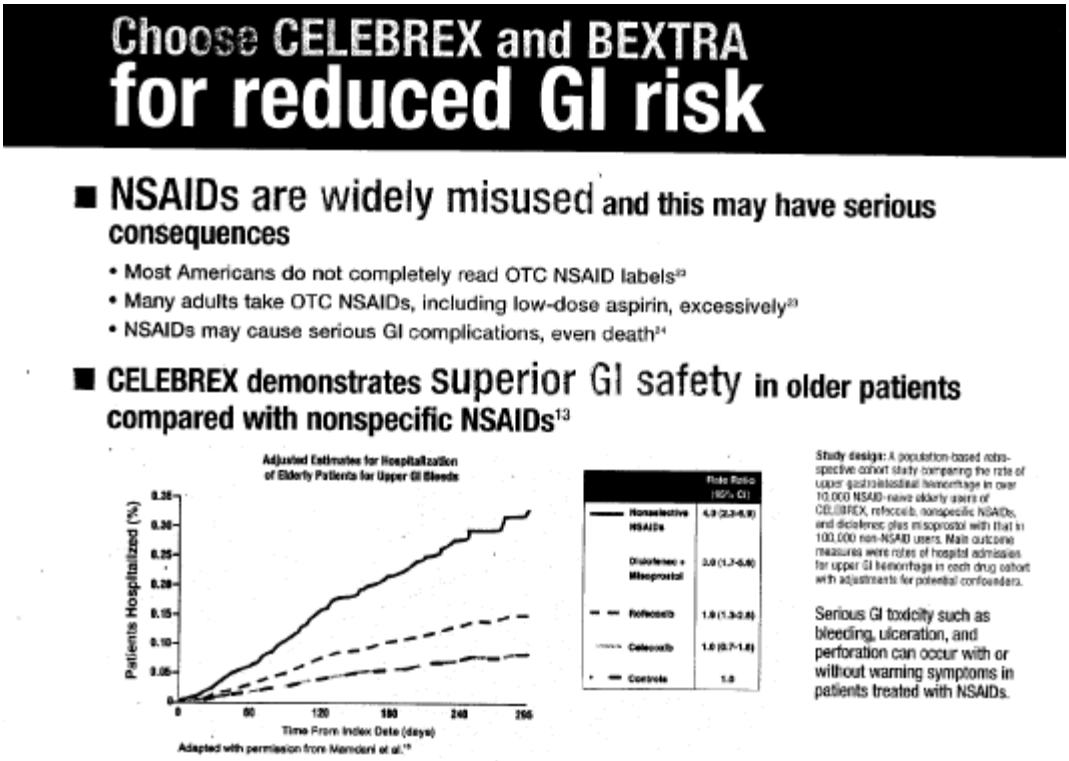
181. This advertisement, which ran during July 2004, overstates the effectiveness of Celebrex. The FDA warned Defendants that it was misleading, failed to disclose risk information, and overstated the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials.



182. This advertisement, which ran during July 2000, makes unsubstantiated superiority claims. By comparing the effectiveness of Celebrex to naproxen the advertisement falsely implies that it is superior to other NSAIDs. The statement "Excellent GI tolerability" is false and misleading, particularly in light of the reference to GI complications for NSAIDs with no such mention of complications for Celebrex. Further, contrary to the advertisement's claim, Celebrex did not show excellent GI tolerability. Rather, its tolerability was no different than NSAIDs and in fact the CLASS study showed increased complications from Celebrex.

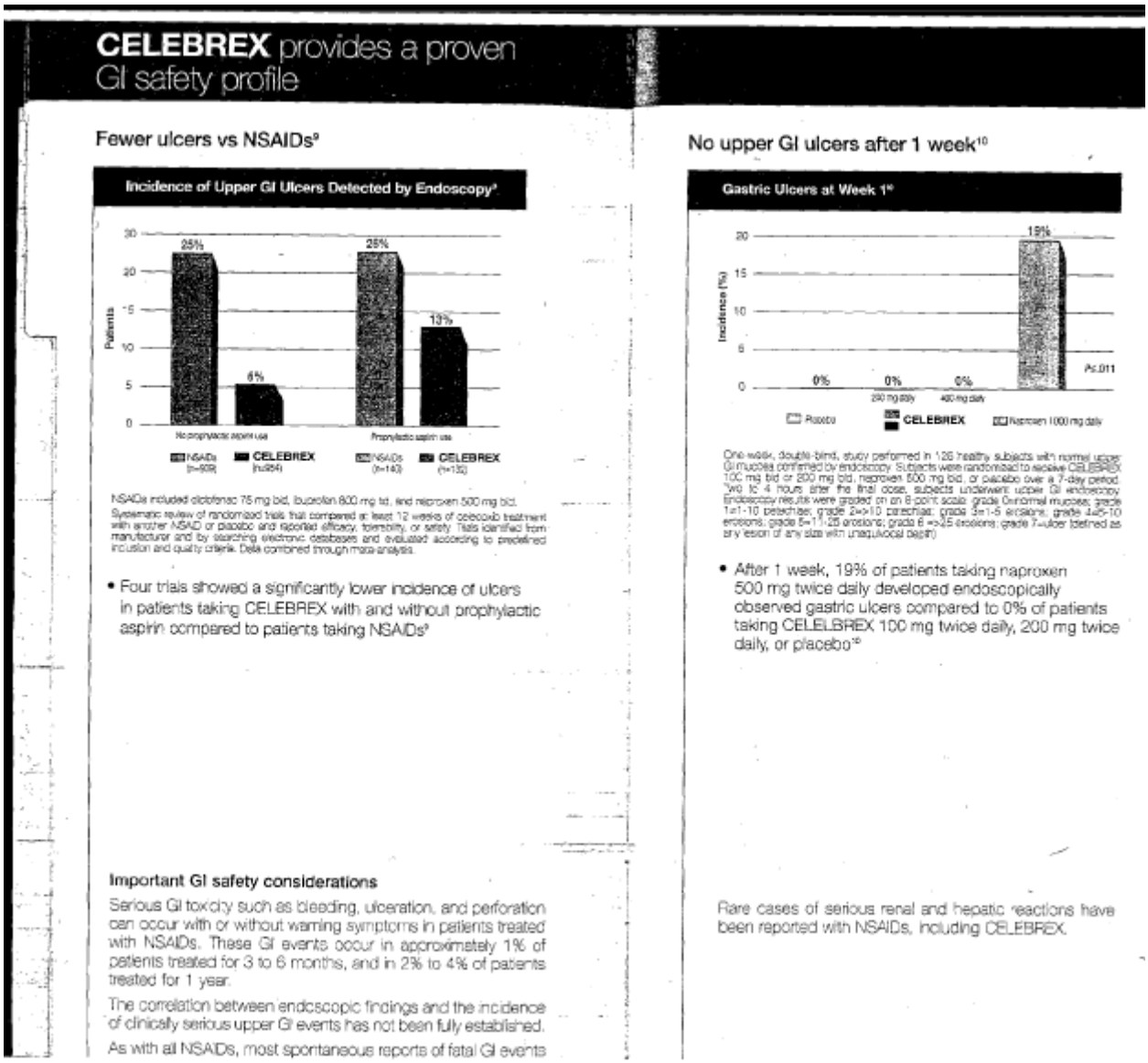


183. This advertisement, which ran during November 1999, makes unsubstantiated superiority claims. By comparing the effectiveness of Celebrex to naproxen the advertisement falsely implies that it is superior to other NSAIDs, and falsely claims that there are "significantly fewer GI ulcers" when in fact this is not statistically proven. This advertisement is misleading by referring to significantly lower endoscopic ulcers, which the FDA found not to be significant, and is further misleading for its failure to balance that statement with the FDA finding that Celebrex was not safer than NSAIDs. In addition, by referring to NSAIDs and GI complications without reference to Celebrex and GI complications, the advertisement is unbalanced and misleading.



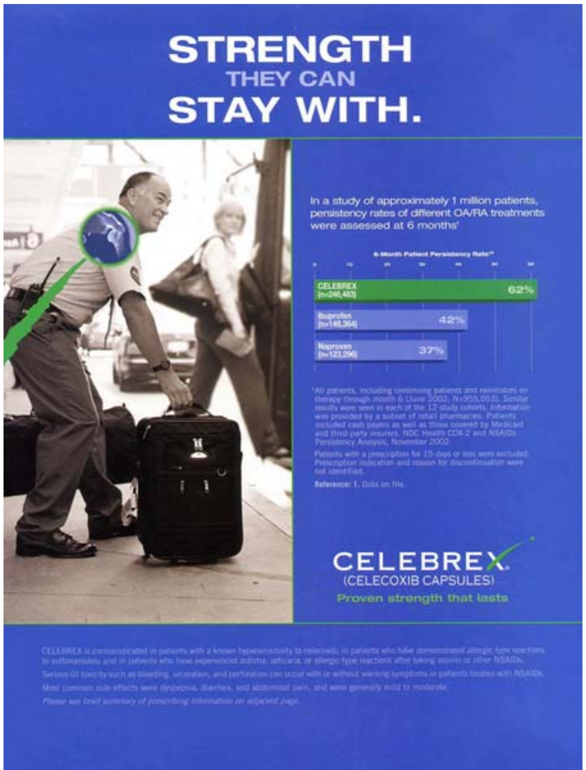
184. This excerpt from an October 2003 brochure disseminated to formulary decision makers falsely touts the GI superiority of Celebrex.[8] The Defendants' scare campaign against traditional NSAIDs is designed to discourage their use while falsely implying Celebrex has less comparable GI toxicity. The advertisement provides an example of another of Defendants' misleading marketing weapons – namely, portraying subsets of data from studies in graphic formats that purport to show benefits of Celebrex supported by scientific data, but which are not scientifically supportable, since the subset was not part of the original study. The FDA warned the Defendants that use of such subcategories of data would be misleading in advertisements. The Defendants, however, continued to use this tool of manipulation throughout their marketing campaigns for Celebrex.

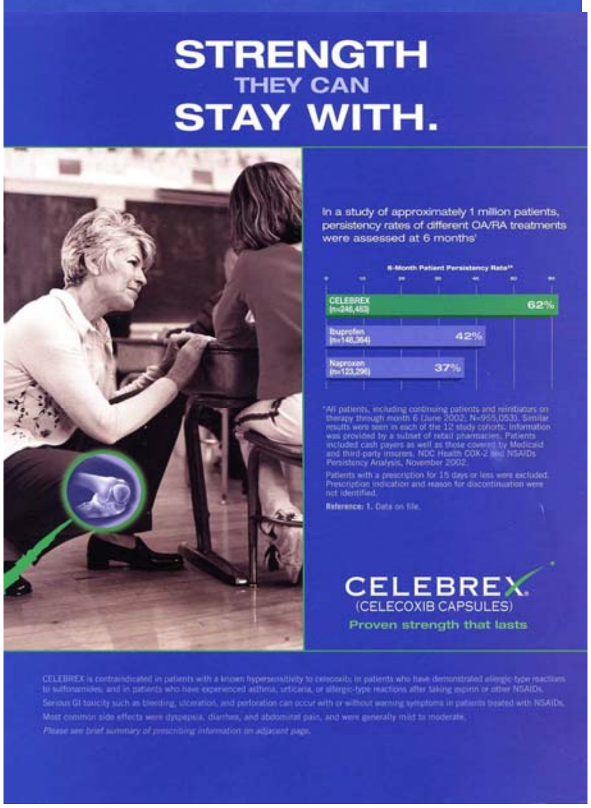
[8] This excerpt appears on bates number Cele NDA 20-998 00020136 of Defendants' document attached hereto as Exhibit 1.



185. This excerpt of an October 2003 brochure entitled "Important Information for Orthopedic Specialists" falsely portrays Celebrex as superior to NSAIDs.[9] The advertisement insists, falsely, that such a proclamation of superiority is "proven." The advertisement is false because, as the Defendants knew and as the FDA had repeatedly commented, there is no scientific basis for such a superiority claim. Such advertisements caused doctors to prescribe Celebrex based on Defendants' unsubstantiated and inaccurate claims.

[9] This excerpt appears on bates number Phelan-K 10000566225 of Defendants' document attached hereto as Exhibit 2.





186. The above three advertisements, which ran during February and March 2004, are misleading. In a letter to Pfizer the FDA stated: "The print ad features the prominent headline "Strength They Can Stay With" and shows a chart comparing Celebrex, Ibuprofen and Naproxen,

titled "6-Month Patient Persistency Rate." Over the chart is the statement, "In a study of approximately 1 million patients, persistency rates of different OA/RA treatments were assessed at 6 months." The tagline below the Celebrex logo in the print ad is "Proven strength that lasts."

187. In the letter to Pfizer, the FDA stated:

> The above referenced claims imply that Celebrex is more effective (*i.e.*, stronger) than ibuprofen and naproxen for treatment of osteoarthritis or rheumatoid arthritis and that patients "stay with" or are more compliant with Celebrex therapy than the compared products. We are not aware of substantial evidence or substantial clinical experience to support these claims. The cited retrospective retail pharmacy database analyses by NDC Health, "Persistency Analysis: Celebrex, Vioxx, and All Other NSAIDs," August 2002 and "Persistency Analysis: Celebrex, Vioxx, Ibuprofen, and Naproxen," from November 2002 (almost two years ago), do not contain any data or information demonstrating that patients found Celebrex to be more effective than the other products, or that patients will be more "persistent" or compliant with Celebrex therapy. Moreover, the database information did not note the indication for which the drug was prescribed, so the suggestion that these rates reflect specifically OA/RA patients is misleading. In addition, the analyses do not account for factors that affect persistence or compliance such as cost insurance coverage, side effects, dosage regimen, and ease of use. Therefore, the analyses do not constitute substantial evidence or substantial clinical experience demonstrating that OA/RA patients are more compliant with Celebrex or stay on Celebrex longer because it is more effective than other products for the treatment of OA or RA.

I. False Promotion of Cardiovascular Safety

188. The CLASS studies published in 2000 assessed the incidence of clinically significant upper GI events seen over one year of treatment with Celebrex, compared to ibuprofen and diclofenac. A post-hoc analysis was done between those patients taking low-dose aspirin for cardioprotection and those patients not taking low-dose aspirin. The published article found that the incidence of cerebrovascular accident, myocardial infarction, and angina was not statistically different among patients taking the three drugs. However, the published data only reflected a 6-month period, used by the company to espouse an unsupportable claim of decreased GI toxicity.

189. The 12-month data set available from the FDA revealed that the rate of combined anginal adverse events was 1.4% in the celecoxib group versus 1.0% in either NSAID group. This tendency toward increased cardiovascular toxicity was described by the FDA Medical Officer Dr. Witter, "[f]or anginal disorders (especially the combined disorders), ***there seems to be a trend***

toward more [cardiac adverse] events in those patients receiving celecoxib, regardless of aspirin use." Had the results of the Alzheimer's study completed in 1999 been made available to the FDA, its Medical Officers surely would have given this finding greater significance.

190. This trend toward more cardiac adverse events was ***magnified*** in those patients not taking low-dose aspirin. Combined anginal disorders were increased in these patients; the celecoxib group had 0.6% vs. 0.2% and 0% in the diclofenac and ibuprofen groups, respectively. There were also more combined atrial serious cardiac adverse events with celecoxib, 0.3% compared to 0.1% and 0% in the diclofenac and ibuprofen groups, respectively. Dr. Witter commented, "In the non-aspirin users, there appears to be a slight trend toward more [serious cardiac adverse] events in those patients receiving celecoxib for combined atrial and anginal disorders." Additionally, the rate of myocardial infarction was higher in the celecoxib group, 0.2%, compared with the other two drugs, 0.1%. Dr. Witter also referred to data from the original NDA for celecoxib in his discussion, "[t]here were suggestions of a dose-response relationship (…100 mg BID celecoxib, 0% crude mortality rate vs. 400 mg BID celecoxib, 0.64% crude mortality rate) between cardiovascular mortality and [increased] celecoxib use that could not be adequately addressed by the data."

191. The FDA was concerned enough to order a cardiorenal consult by FDA Medical Officer Dr. Throckmorton on the same CLASS study data. His report noted, "[t]he CLASS trial data do not support a large adverse effect of celecoxib on cardiovascular mortality or on serious adverse events related to thrombosis relative to either diclofenac or ibuprofen. The data do not exclude a less apparent pro-thrombotic effect of celecoxib, such as might be reflected in the relative rates of cardiac adverse events related to ischemia."

192. The FDA further determined that valuable CV safety data showing that Celebrex had similar cardiovascular toxicity to ibuprofen and diclofenac be added to the label. The Defendants falsely promoted these additions to the Celebrex label as a "reaffirm[ance]" by the FDA of Celebrex's CV safety profile. In a June 7, 2002 press release, Defendants announce that the required label changes, "reaffirms the cardiovascular safety profile of Celebrex." This statement is false especially in light of the changes made to the label including the inclusion of the

additional cardiovascular adverse events, "angina pectoris, coronary artery disorder, [and] myocardial infarction" to the Adverse Reactions section of the label.

193. The Defendants' massive marketing campaign proclaimed that CLASS revealed no cardiovascular signals. In an August 2001 Dear Patient letter provided to doctors for distribution to their patients, Defendants claimed,

> [y]ou may have seen recent news reports about safety issues, specifically heart attacks and strokes, involving our prescription arthritis drug, CELEBREX® (celecoxib capsules). We are concerned that these reports may have caused you to worry about taking CELEBREX. We want to assure you that CELEBREX has demonstrated no increased risk for heart attack and stroke compared with commonly used arthritis medications such as naproxen and ibuprofen, against which it was studied in more than 40,000 patients.

This was materially false and caused doctors to prescribe Celebrex, and End-Payors to purchase it.

194. In a June 7, 2002 press release regarding the Celebrex label revision that resulted from the CLASS studies, and even though in internal documents CV additions to the label were described by Defendants as a "worse case scenario," Defendants proclaimed,

> [t]he revised label reaffirms the cardiovascular safety profile of CELEBREX…Additionally, the CELEBREX cardiovascular safety profile is supported by the studies conducted for the [NDA] and other post-marketing surveillance worldwide covering an estimated 34.5 million patients or 17.25 million patient-years of exposure…and is consistent with data reported to the FDA.

These statements were false because they implied that Celebrex actually had a superior cardiovascular safety profile, and that the FDA agreed. However, no such superiority claim was evidenced in either the scientific data available or in Celebrex's approved labeling.

195. To the contrary, the FDA reviewers' recommendations regarding the CLASS data were,

> Our findings suggest a potential increase in cardiovascular event rates for the presently available COX-2 inhibitors … definitive evidence of such an adverse effect will require a prospective randomized clinical trial …. Given the remarkable exposure and popularity of this new class of medications, we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents. Until then, we urge caution in prescribing these agents to patients at risk for cardiovascular morbidity.

Although employing a placebo group from a different trial weakens the validity of their analysis, the authors' call for a prospective randomized clinical trial powered to truly analyze the cardiovascular risk to benefit ratio was then exactly correct. Recently, however, such a placebo-controlled trial of celecoxib has clearly demonstrated this risk (as did the Alzheimer's study that was completed in 1999, but not disclosed to the FDA in a timely fashion).

196. This trial was the APC colon polyprecurrence prevention study, in which approximately 2,000 patients took celecoxib or a placebo. Interestingly, this was the longest celecoxib trial to date, with a mean duration of treatment of 33 months, as opposed to the much shorter 12-month duration of the CLASS studies. A statistically significant elevation in the risk for a major fatal or non-fatal cardiovascular event (a composite endpoint of cardiovascular death, acute myocardial infarction, and stroke) was seen in those patients taking celecoxib compared to those in the placebo group. This followed a dose-response relationship: the relative risk at 400 mg/day of celecoxib was 2.5 while the relative risk at 800 mg/day was 3.4. Because of this unacceptable danger, the trial was prematurely halted. The FDA released an explanatory statement which said, "While we have not seen all available data on Celebrex, these findings are similar to recent results from a study of Vioxx (rofecoxib), another drug in the same class as Celebrex. Vioxx was recently voluntarily withdrawn by Merck."

197. Given the above data and trends, Defendants' advertising and promotional campaigns touting the cardiovascular safety or superiority of Celebrex were misleading. This trend to promote the CV safety of a drug in the face of increasing scientific data of its CV risk, is even more alarming in view of the 1999 Alzheimer's study that was unpublished and showed patients taking Celebrex were more likely than those taking a placebo to have heart attacks. Though the study was small, its conclusions contradicted years of claims by Defendants that no trial of Celebrex had ever shown adverse cardiac results.

198. The Alzheimer's study, Defendants' protocol number IQ5-97-02-001, was completed June 24, 1999 and compared Celebrex to placebo for the slowing of the progression of Alzheimer's Disease and overall safety. In this study, patients taking Celebrex were 3.6 times more likely to experience a serious cardiovascular event (2.1% of patients taking placebo vs. 7.7%

of patients taking Celebrex).[10] Defendants' internal, final report of this study shows that the increased risk of cardiovascular complications in patients taking Celebrex was statistically significant.[11] Furthermore, among patients taking Celebrex there were 12% more serious adverse events (25.6% vs. 22.9%) and 59% more deaths (4.6% vs. 2.9%). The study was never published and was not presented to the FDA in time to be included in the February 2001 Advisory Committee Meeting that considered the safety of Celebrex. Had the findings from this study been published and disclosed to the FDA in a timely manner, sales of Celebrex – based primarily on the claimed safety advantage over older, less expensive NSAIDs – would have been dramatically less. These findings would have been material to prescribing doctors given the concern, appropriately expressed in the JAMA article reporting the first six months of the CLASS study, about the theoretical risk of increased adverse events disturbing the clotting balance with selective COX-2 inhibition:

> Although it has been hypothesized that COX-2 specific inhibitors might increase the risk of cardiovascular thromboembolic events via inhibition of vascular prostacyclin synthesis without a corresponding inhibition of platelet thromboxane, no such increase was evident in the current study.

Defendants' promotion of the cardiovascular safety of Celebrex despite the results of this study are particularly vexing, because it was completed eight months before the CLASS study was completed, and its results should have informed the report published in JAMA.

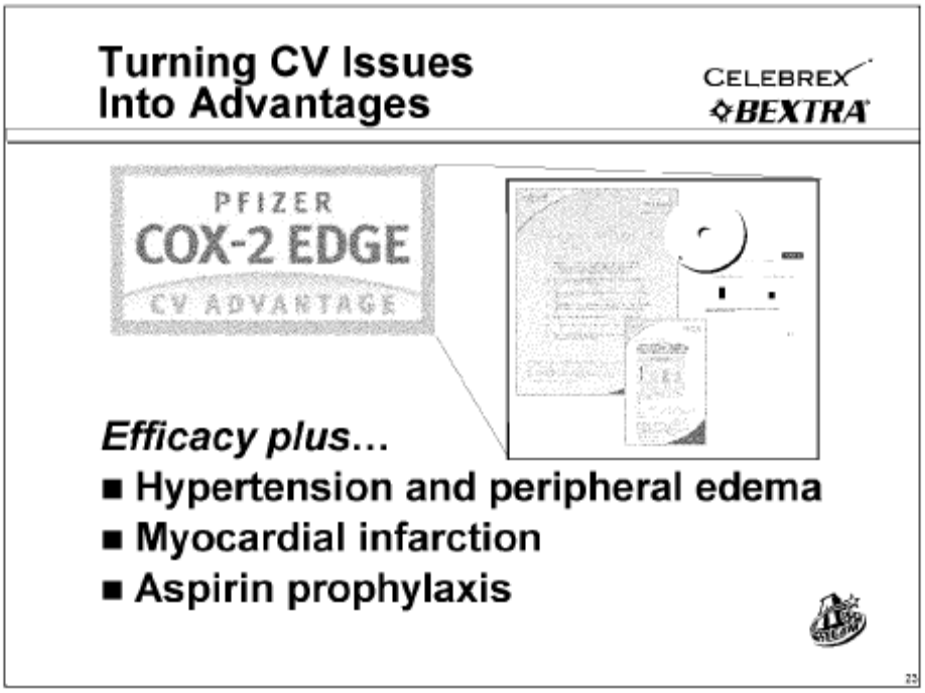
199. Defendants' 1999 results as to the CV risks presented by Celebrex were confirmed in a study by New Zealand's Medical Research Institute, which found that patients taking Celebrex had a cardiovascular risk as great as those taking Vioxx.

200. Despite these clear indications of cardiovascular risk, Defendants' geared their marketing strategy to tout the CV safety of Celebrex over other NSAIDs. The following excerpt from a sales training presentation in April of 2004 demonstrates that Defendants entire marketing

[10] Letter to FDA revealing heart dangers in an unpublished clinical trial of Celebrex (HRG Publication #1721), Public Citizen, January 31, 2005. http://citizen.org/publications/release.cfm?ID=7359.

[11] A statistically significant difference favoring placebo in adverse events was observed for certain CV-related body system terms (Cardiovascular Disorders, General; Heart Rate and Rhythm Disorders; Myo, Endo, Pericardial & Valve Disorders). These differences were primarily driven by the individual terms cardiac failure, fibrillation atrial, and angina pectoris. http://www.clinicalstudyresults.org/documents/company-study_76_0.pdf.

strategy regarding CV risks involved converting those risks into a selling tool. The slide is misleading because it falsely promotes Celebrex as having a CV advantage over other NSAIDs. It also falsely implies that Celebrex is actually cardiovascularly safe, even though Celebrex was required to carry a warning of CV adverse events in its label.[12]



In concert with Bruce and Amy, we have selected 4 important selling tools to highlight today which provide the foundation outlining selling messages and materials for planning in advance of the Ft Lauderdale Meeting. .

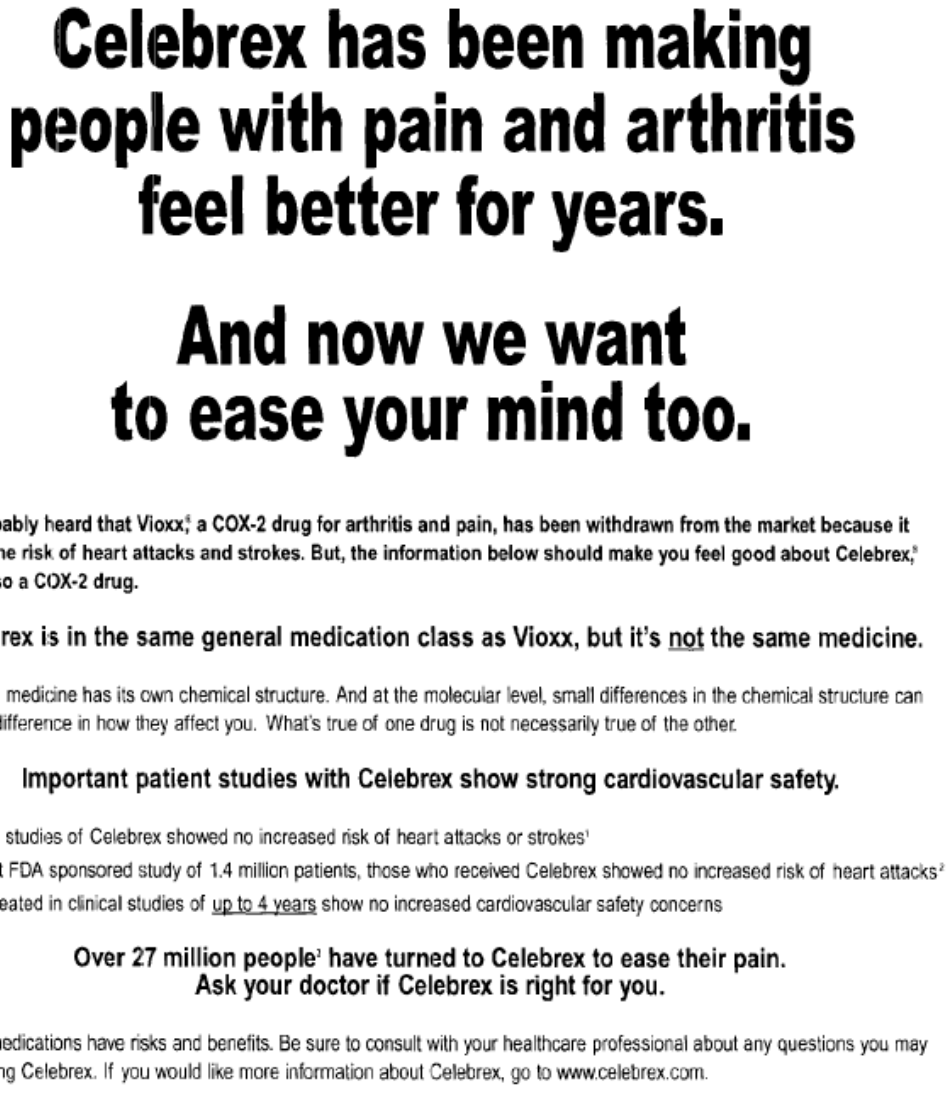
The first of 2 clinical issues tools to help expand time and identify patients who would benefit from the efficacy and safety of Bextra and Celebrex is the Cox-2 Edge CV Advantage Kit. The CV kit begins with a 4-page Flashcard presenting portfolio efficacy and safety advantages.

A kit contains a slide set on CD presenting the clinical advantages of our Cox-2 portfolio in patients with hypertension, peripheral edema, history of MI and are taking cardioprotective aspirin. The tools in this kit represent additional and important messages to help representatives identify patients who may benefit from Bextra and Celebrex.

Consider recommending your team use this kit to build upon the master visual aid to support dinner programs, lunch n learns, and small group presentations . Of special note several elements of this kit are also leave-behinds, including the slide set.

[12] This excerpt appears on bates number DeShon-D 10000001233 of Defendants' document attached hereto as Exhibit 3 .

201. In the following advertisement, Defendants tell consumers they want to "ease your mind" about Celebrex and show them its "strong cardiovascular safety." This advertisement is misleading because Celebrex was not "safe" cardiovascularly. To the contrary, it had a specific warning of cardiovascular adverse events in its FDA approved label. Defendants went even further though, and pronounced that Celebrex has "strong cardiovascular safety." Such a claim is false, directly contradicted the FDA approved labeling, and caused doctors to prescribe and consumers to purchase Celebrex.[13]



Celebrex has been making people with pain and arthritis feel better for years.

And now we want to ease your mind too.

You've probably heard that Vioxx,[4] a COX-2 drug for arthritis and pain, has been withdrawn from the market because it increased the risk of heart attacks and strokes. But, the information below should make you feel good about Celebrex,[5] which is also a COX-2 drug.

Celebrex is in the same general medication class as Vioxx, but it's not the same medicine.

Each COX-2 medicine has its own chemical structure. And at the molecular level, small differences in the chemical structure can make a big difference in how they affect you. What's true of one drug is not necessarily true of the other.

Important patient studies with Celebrex show strong cardiovascular safety.

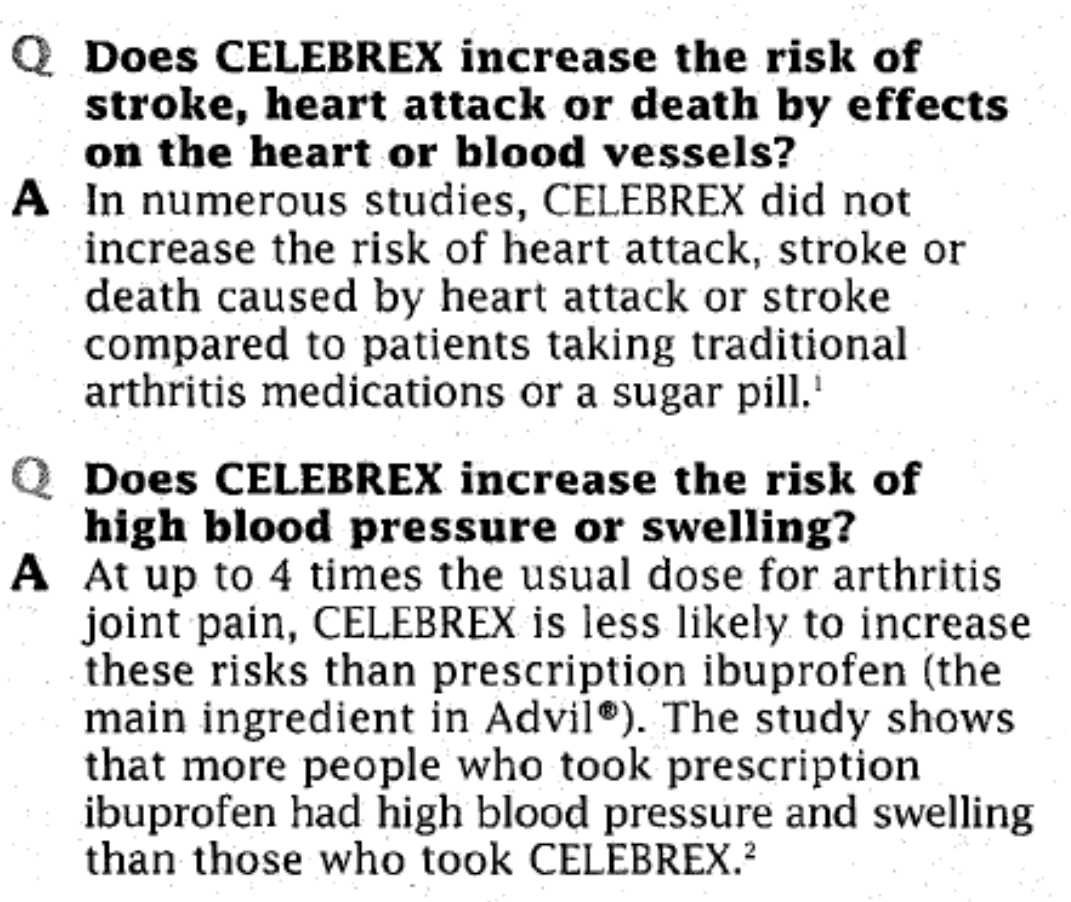
- Numerous studies of Celebrex showed no increased risk of heart attacks or strokes[1]
- In a recent FDA sponsored study of 1.4 million patients, those who received Celebrex showed no increased risk of heart attacks[2]
- Patients treated in clinical studies of up to 4 years show no increased cardiovascular safety concerns

Over 27 million people[3] have turned to Celebrex to ease their pain.
Ask your doctor if Celebrex is right for you.

Of course, medications have risks and benefits. Be sure to consult with your healthcare professional about any questions you may have regarding Celebrex. If you would like more information about Celebrex, go to www.celebrex.com.

[13] This excerpt appears at bates number CeleNDA 20-998 00023822 of Defendants' document attached hereto as Exhibit 4.

202. The advertisement below, which was part of a Q&A reference disseminated to consumers, is false and misleading in that it states that Celebrex does not increase cardiovascular risk, implies that there are no studies that show that Celebrex does increase the risk for heart attacks, strokes and death, and made the very claims that Celebrex is superior to other NSAIDs in terms of cardiovascular safety which the FDA did not permit.[14]



Q Does CELEBREX increase the risk of stroke, heart attack or death by effects on the heart or blood vessels?

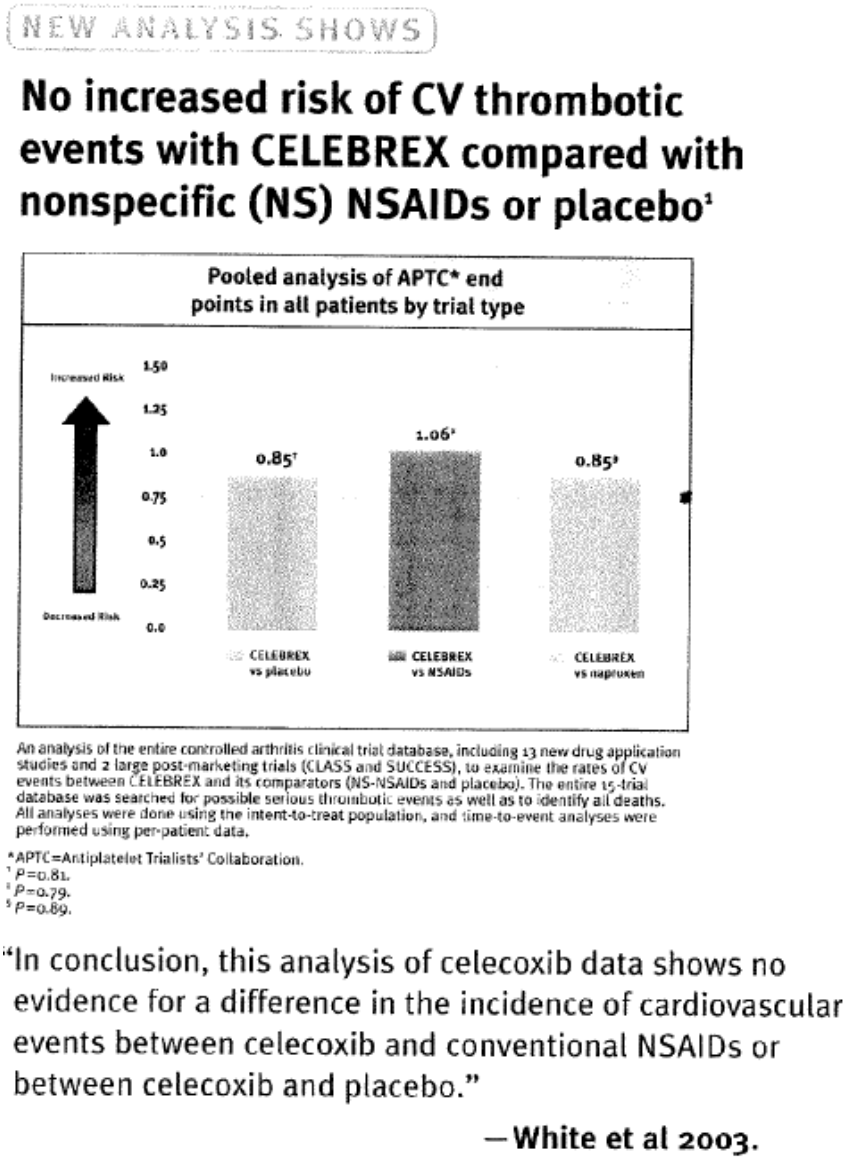
A In numerous studies, CELEBREX did not increase the risk of heart attack, stroke or death caused by heart attack or stroke compared to patients taking traditional arthritis medications or a sugar pill.[1]

Q Does CELEBREX increase the risk of high blood pressure or swelling?

A At up to 4 times the usual dose for arthritis joint pain, CELEBREX is less likely to increase these risks than prescription ibuprofen (the main ingredient in Advil®). The study shows that more people who took prescription ibuprofen had high blood pressure and swelling than those who took CELEBREX.[2]

[14] This excerpt appears at bates number Cele NDA 20-998 00023927 of Defendants' document attached hereto as Exhibit 5.

203. The following advertisement falsely proclaims that Celebrex is cardiovascularly safer than both traditional NSAIDs and placebos. The advertisement also lacks fair balance because it includes another marketing trick the Defendants employed frequently, namely, using studies conducted and reported by investigators on Defendants' payroll to support false claims. Such studies are set up so as to mask any safety risks and inflate efficacy data. Such studies were cited, copied and distributed without adequate disclosure of the authors' connections to the Defendants.[15]



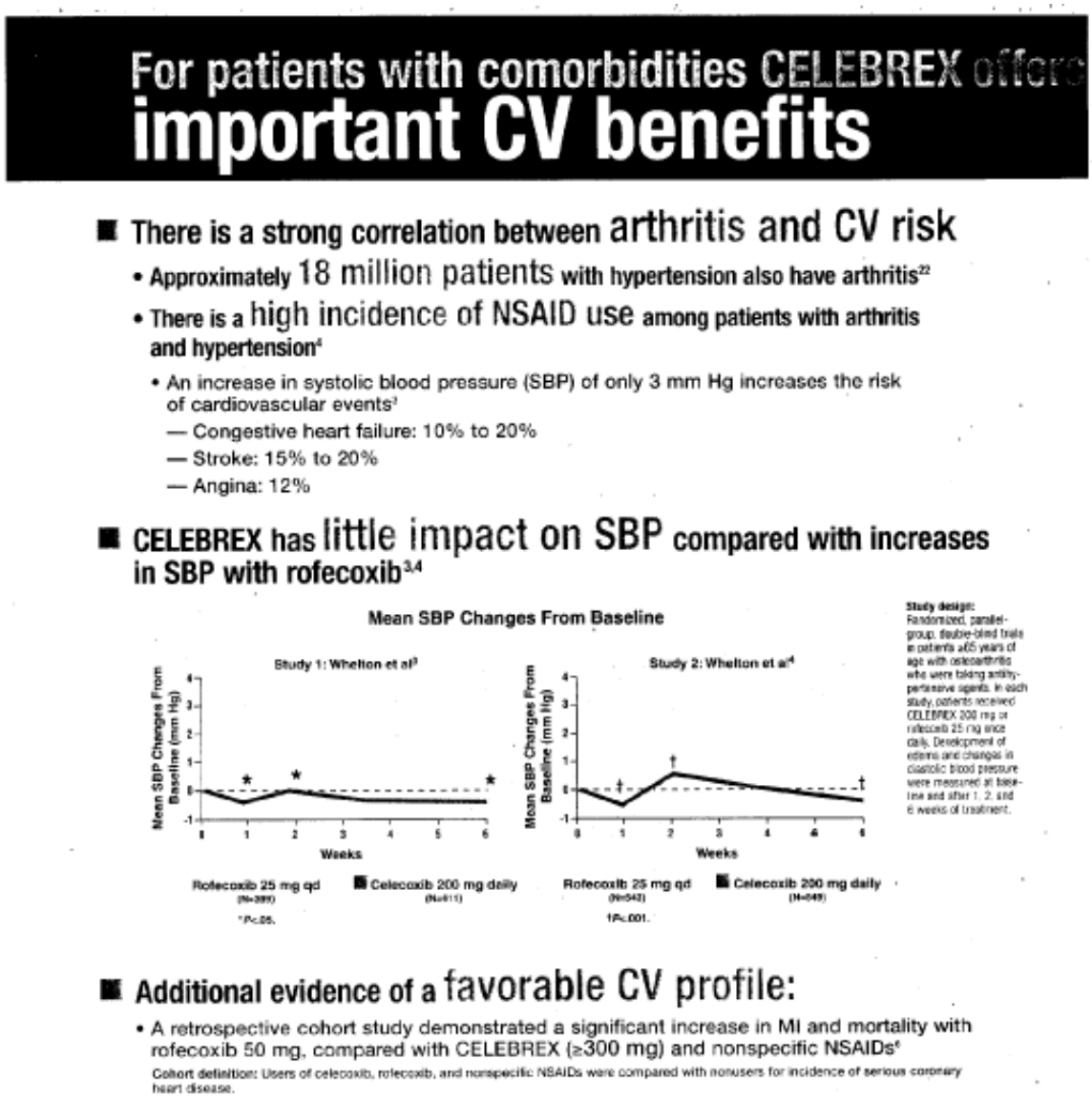
[15] The referenced excerpt appears at bates number Cele NDA 20-998 00022355 of Defendants' document attached hereto as Exhibit 6 .

204. In contrast to the prominent display and wide dissemination of studies that Defendants used to highlight alleged advantages of Celebrex, scientific articles that portrayed Celebrex in a negative light, actually showing that it was more cardiovascularly dangerous that traditional NSAIDs, were not included in advertisements, and Defendants' sales force were directed to steer doctors' attention away from them. For example, in one letter to "Colleagues" found in the file of a member of Defendants' marketing team, Defendants' sales force is specifically instructed to steer doctors' attention away from potentially damaging scientific articles. The letter states in part,

> [a]lthough there has been media and physician interest in the Solomon data, we do not want to move our focus away from selling the benefits of Celebrex and Bextra.
>
> Be diligent in reminding representatives the Solomon data are not to be proactively detailed. Instead, ask your representatives to be prepared to redirect the detail back to the Pfizer COX-2 portfolio.

Such marketing methods are misleading, and were not approved by the FDA or the FDA label, in that they fail to present a fair balance of the scientific data known regarding Celebrex. Instead, they cause doctors and consumers to incorrectly believe that the superiority and safety claims presented represent an accurate picture of the drug.

205. The following advertisement was directed to formulary decision makers in October 2003, and falsely proclaims that Celebrex has "important CV benefits" and has a "favorable CV profile." Such claims are false because they are unsupported by unbiased scientific data, are not a fair and balanced presentation of scientific data and are not consistent with Celebrex's approved labeling.[16]



For patients with comorbidities CELEBREX offers
important CV benefits

■ There is a strong correlation between arthritis and CV risk
- Approximately 18 million patients with hypertension also have arthritis[22]
- There is a high incidence of NSAID use among patients with arthritis and hypertension[4]
  - An increase in systolic blood pressure (SBP) of only 3 mm Hg increases the risk of cardiovascular events[3]
    - — Congestive heart failure: 10% to 20%
    - — Stroke: 15% to 20%
    - — Angina: 12%

■ CELEBREX has little impact on SBP compared with increases in SBP with rofecoxib[3,4]

Mean SBP Changes From Baseline

Study 1: Whelton et al[3]

Study 2: Whelton et al[4]

Mean SBP Changes From Baseline (mm Hg)

Weeks

Rofecoxib 25 mg qd

Celecoxib 200 mg daily

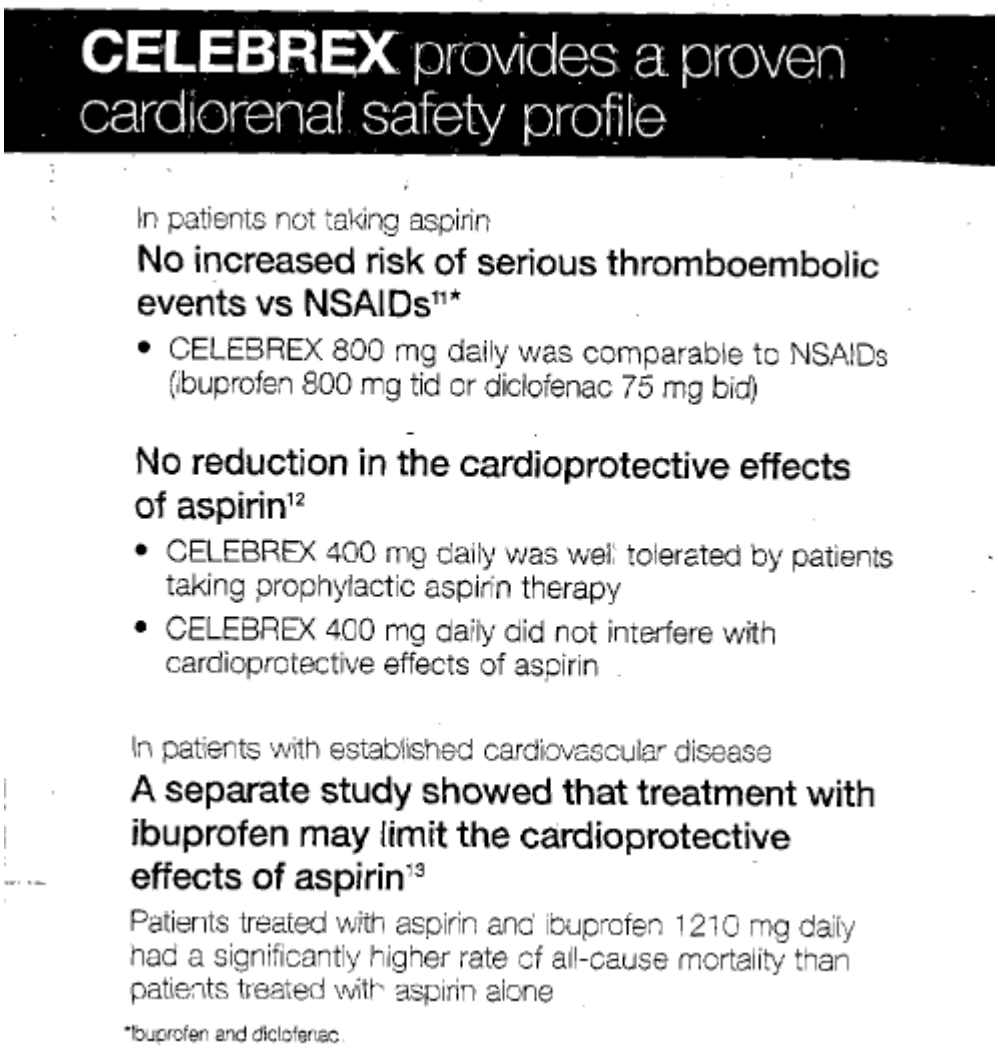
Study design: Randomized, parallel-group, double-blind trials in patients ≥65 years of age with osteoarthritis who were taking antihypertensive agents. In each study, patients received CELEBREX 200 mg or rofecoxib 25 mg once daily. Development of edema and changes in diastolic blood pressure were measured at baseline and after 1, 2, and 6 weeks of treatment.

■ Additional evidence of a favorable CV profile:
- A retrospective cohort study demonstrated a significant increase in MI and mortality with rofecoxib 50 mg, compared with CELEBREX (≥300 mg) and nonspecific NSAIDs[5]

Cohort definition: Users of celecoxib, rofecoxib, and nonspecific NSAIDs were compared with nonusers for incidence of serious coronary heart disease.

[16] The referenced excerpt appear at bates number Cele NDA 20-998 00020135 of Defendants' document attached hereto as Exhibit 7.

206. In a brochure entitled "Important information for Orthopedic Specialists" produced and distributed by Defendants in September 2003, Defendants falsely claim that "CELEBREX provides a proven cardiorenal safety profile. Such claims are misleading in that they fail to include significant risk information known to Defendants and contained in the FDA approved label regarding cardiovascular and renal risks. The bold statement at the beginning of the advertisement that "CELEBREX provides a proven cardiorenal safety profile" improperly downplays any risk information found in small print later in the advertisement. Such marketing devices are misleading and had been repeatedly criticized by the FDA.[17]



CELEBREX provides a proven cardiorenal safety profile

In patients not taking aspirin

No increased risk of serious thromboembolic events vs NSAIDs[11]*

- CELEBREX 800 mg daily was comparable to NSAIDs (ibuprofen 800 mg tid or diclofenac 75 mg bid)

No reduction in the cardioprotective effects of aspirin[12]

- CELEBREX 400 mg daily was well tolerated by patients taking prophylactic aspirin therapy
- CELEBREX 400 mg daily did not interfere with cardioprotective effects of aspirin

In patients with established cardiovascular disease

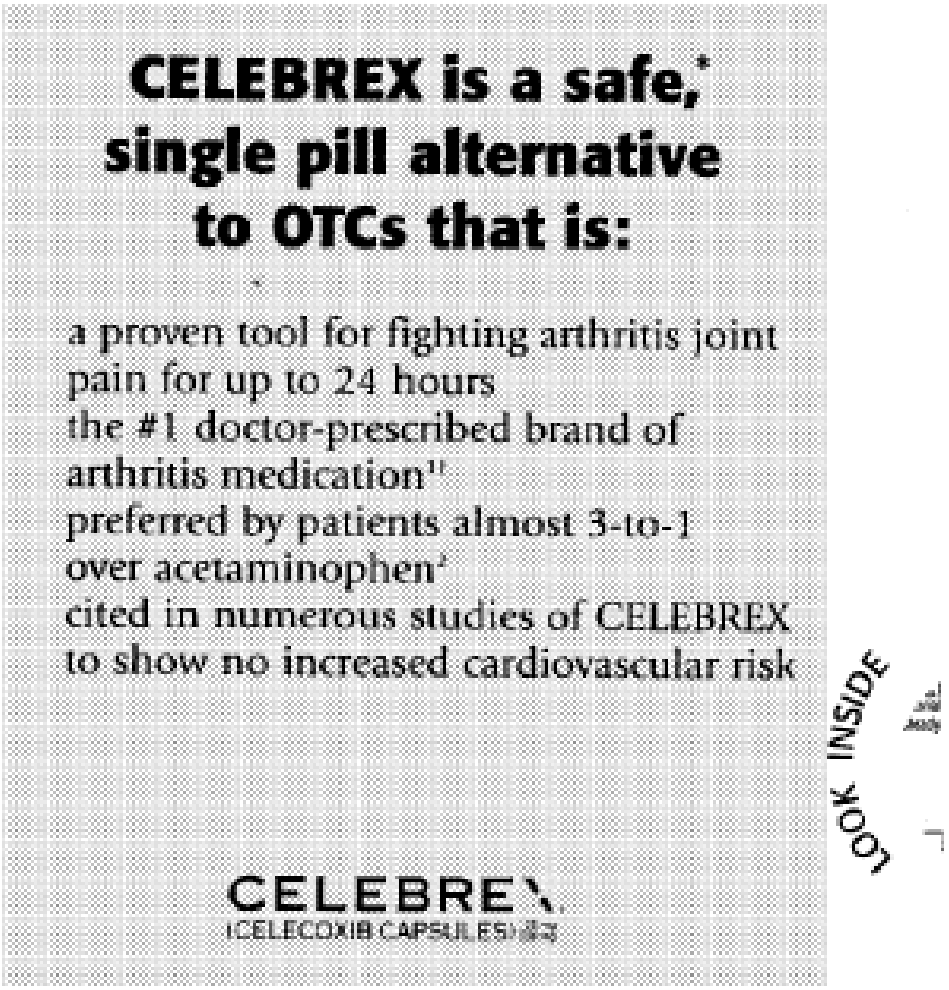
A separate study showed that treatment with ibuprofen may limit the cardioprotective effects of aspirin[13]

Patients treated with aspirin and ibuprofen 1210 mg daily had a significantly higher rate of all-cause mortality than patients treated with aspirin alone

*Ibuprofen and diclofenac.

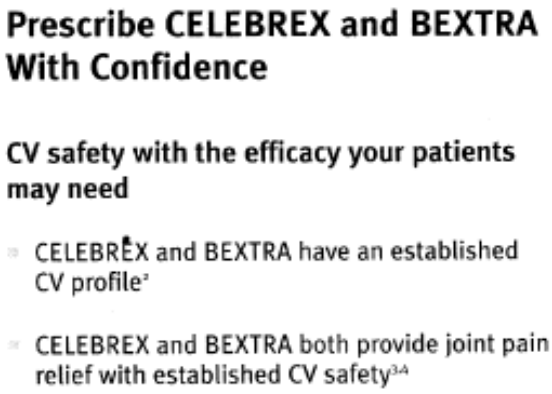
[17] The referenced excerpt appears at bates number Phelan-K 10000566225 of Defendants' document attached hereto as Exhibit 8.

207. In the following direct-to-consumer mailing, Defendants falsely promoted Celebrex as not only cardiovascularly safe, but also as superior to over-the-counter alternatives. The statement, "cited in numerous studies of CELEBREX to show no increased cardiovascular risk," is misleading in that it implies that there are no studies that demonstrate a cardiovascular risk – which in fact there were.[18]



[18] The referenced excerpt appears at bates number Cele NDA 20-998 00378949 of Defendants' document attached hereto as Exhibit 9.

208. Defendants' false promotions of the cardiovascular safety and superiority of Celebrex were also directed towards doctors and Third-Party Payors. In the following advertisement, doctors are told to prescribe Celebrex with confidence because it has the "CV safety with the efficacy your patients may need." This advertisement is false because it proclaims that Celebrex has an established CV safety profile – a claim that contradicts its FDA approved labeling and implies that there is no scientific data showing a cardiovascular risk.[19]



Prescribe CELEBREX and BEXTRA With Confidence

CV safety with the efficacy your patients may need

- CELEBREX and BEXTRA have an established CV profile[2]
- CELEBREX and BEXTRA both provide joint pain relief with established CV safety[3,4]

209. Defendants similarly targeted Third-Party Payors with their false promotional campaign of cardiovascular safety. The following excerpt of a direct mail letter to an insurance provider falsely indicates that Celebrex has CV benefits.[20]

CARDIOVASCULAR BENEFIT:
It is also well established that NSAIDs may cause edema and hypertension as well as disrupt the activity of some antihypertensive medications including beta-blockers and angiotensin converting enzyme (ACE) inhibitors.[5]

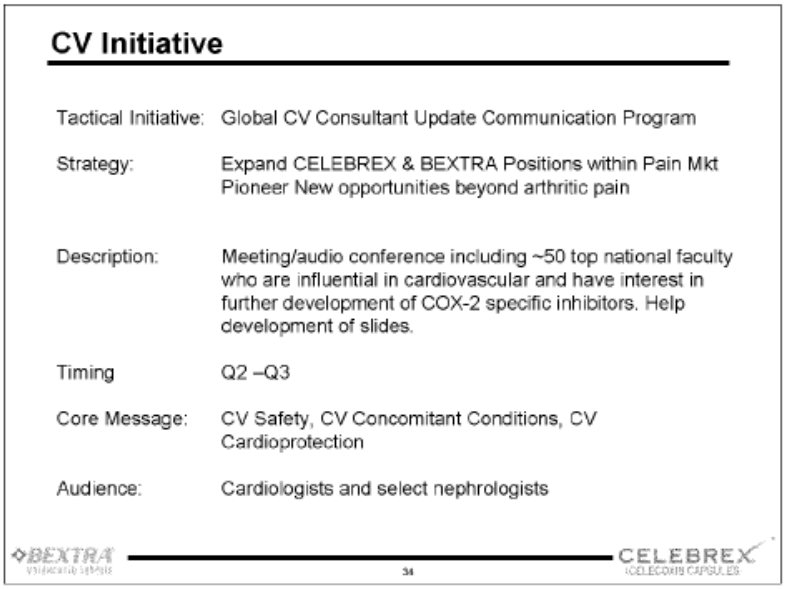
Emerging data on the use of COX-2 specific inhibitors in patients with cardiovascular disease and hypertension have shown that celecoxib is a safe alternative to non-specific NSAIDs in this patient population. To date, several head to head studies have shown significant increases in hypertension, edema, and cardiovascular disease (CV) risk among Vioxx® (rofecoxib) users versus CELEBREX users. Some of the study findings include:

The cited findings are studies performed by investigators with strong links and monetary ties to the Defendants and thus, do not represent the CV profile of Celebrex with fair balance.

[19] The referenced excerpt appears at bates number Cele NDA 20-998 00022355 of Defendants' document attached hereto as Exhibit 10.

[20] The referenced excerpt appears at bates number Cele NDA 20-998 00021756 of Defendants' document attached hereto as 11.

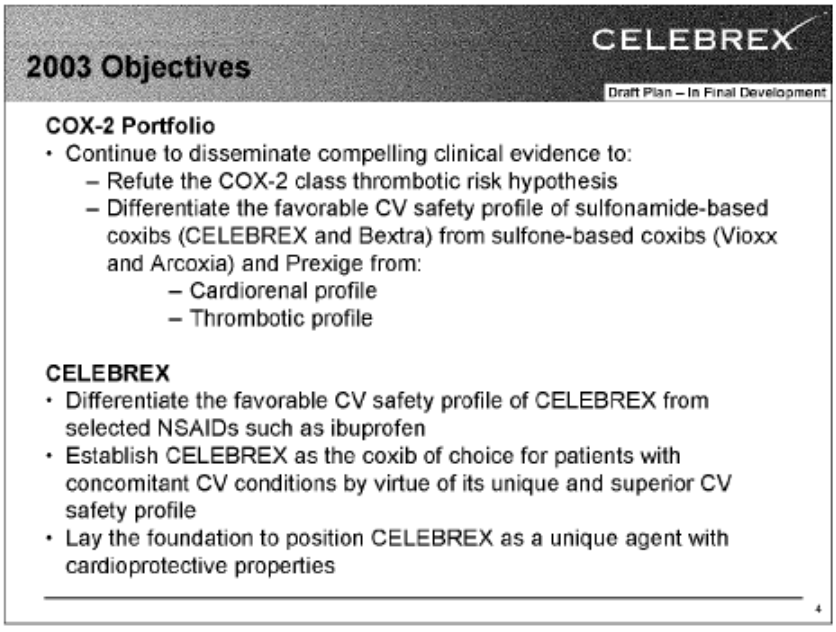
210. ***Defendants did not only market Celebrex as safer cardiovascularly than other NSAIDs; they went even further in contravention of its FDA approved label. Defendants began marketing Celebrex, against a huge body of scientific data, as cardioprotective***. The following are internal marketing slides of Defendants which demonstrate that the promotion of Celebrex as cardioprotective was a core message in their marketing strategy.[21]



CV Initiative

Tactical Initiative:	Global CV Consultant Update Communication Program
Strategy:	Expand CELEBREX & BEXTRA Positions within Pain Mkt Pioneer New opportunities beyond arthritic pain
Description:	Meeting/audio conference including ~50 top national faculty who are influential in cardiovascular and have interest in further development of COX-2 specific inhibitors. Help development of slides.
Timing	Q2 –Q3
Core Message:	CV Safety, CV Concomitant Conditions, CV Cardioprotection
Audience:	Cardiologists and select nephrologists

BEXTRA — 34 — CELEBREX



2003 Objectives

CELEBREX

Draft Plan – In Final Development

COX-2 Portfolio

- Continue to disseminate compelling clinical evidence to:
  - Refute the COX-2 class thrombotic risk hypothesis
  - Differentiate the favorable CV safety profile of sulfonamide-based coxibs (CELEBREX and Bextra) from sulfone-based coxibs (Vioxx and Arcoxia) and Prexige from:
    - Cardiorenal profile
    - Thrombotic profile

CELEBREX

- Differentiate the favorable CV safety profile of CELEBREX from selected NSAIDs such as ibuprofen
- Establish CELEBREX as the coxib of choice for patients with concomitant CV conditions by virtue of its unique and superior CV safety profile
- Lay the foundation to position CELEBREX as a unique agent with cardioprotective properties

4

[21] The referenced excerpts appear at bates numbers DeShon-D 10000005736 and DeShon-D 10000010440, respectively of Defendants' documents attached as Exhibits 12 and 13.

211. The above examples of Defendants' massive marketing scheme are just a fraction of the false and misleading statements that were directed to consumers, health professionals and Third-Party Payors that misrepresented the CV profile of Celebrex. Such false misrepresentations were material since End-Payors would either have purchased less expensive traditional NSAIDs or nothing at all. Defendants knew that such misrepresentations were material, because they were intended to contradict, mask and divert attention away from the Celebrex label listing both CV and GI adverse events, and the scientific data that over time became more and more negative for Celebrex.

212. The Defendants' knowledge of CV risks was evidenced by a letter sent to the FDA on January 31, 2005:

> January 31, 2005
>
> Dr. Lester M. Crawford, Acting Commissioner
> Food and Drug Administration
> 5600 Fishers Lane
> Rockville, MD 20857
>
> Dear Dr. Crawford,
>
> Since filing our petition last week (January 24th) to immediately ban celecoxib (Celebrex) and valdecoxib (Bextra)[1] ***we have discovered the results of an unpublished randomized placebo-controlled study of Pfizer***, finished more than four years ago, that showed a significantly increased rate (3.5-fold) of serious cardiovascular adverse events and ***more than a doubling in the rate of cardiovascular deaths in people using celecoxib compared to those using a placebo in a study concerning Alzheimer's disease.*** (Emphasis added.)
>
> * * *
>
> The combined rate of all serious cardiovascular adverse events in patients getting a placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6-fold increase in cardiovascular risk in those people taking celecoxib. (p=0.03)
>
> * * *
>
> Thus, there was a statistically significant increase in the composite of all serious cardiovascular events in patients getting Celebrex compared to patients getting a placebo.

213. Defendants falsely promoted Celebrex as safe, without reference to the risks present in the FDA approved label, because reference to such risks would decrease sales. Since its "Black Box" warning concerning cardiovascular risks issued in August 2005, which constitutes only a partial disclosure, Celebrex sales have dropped by 48%.

J. Pfizer Temporarily Halts the Celebrex Promotional Scheme

214. On or about September 30, 2004, Merck withdrew its COX-2 inhibitor, Vioxx from the marketplace. In response, Pfizer issued a statement indicating it was "confident in the long term cardiovascular safety of Celebrex" and indicated that "since the introduction of COX-2 inhibitors, the rate of hospitalizations for gastrointestinal events associated with long term arthritis treatment has declined significantly."

215. The foregoing statement was misleading in that it touted the cardiovascular safety of Celebrex and did not present the cardiovascular risks included in the Celebrex label. There was no statistically significant evidence to support the claim that Celebrex or other COX-2 inhibitors lead to a decrease in serious GI complications. In fact, data from a Canadian study shows that after COX-2 inhibitors became available in 2000 there was a 41% increase in NSAID use (accounted for entirely by COX-2 inhibitors) and a 10% increase in the hospitalization rate for GI bleeding – belying the claim above.[22]

216. On December 17, 2004, Pfizer shocked consumers by disclosing a study that demonstrated an increased risk of cardiovascular disease (the 1999 Alzheimer's study referred to above). Pfizer then announced on December 20, 2004, that it would stop all television, radio, newspaper and magazine advertising. Pfizer did so because it was aware that its previous campaign was misleading.

217. On February 1, 2005, Pfizer finally admitted it was aware of the 1999 Alzheimer's clinical trial finding that elderly patients using Celebrex were far more likely to suffer heart problems than patients taking a placebo. The study was never published and was not submitted to the FDA until 2001, four months after the FDA's review of Celebrex and Vioxx. As stated by

[22] Mamdani M., Jurlink D.N., Kopp A., et al., Gastrointestinal bleeding after the introduction of COX-2 inhibitors: ecological study, *British Medical Journal Online*: http://bmj.bmjjournals.com/cgi/reprint/bmj.38068.716262.F7v1.

David Graham, MD, MPH, of the FDA, in an editorial in the Journal of the American Medical Association (JAMA) in September of 2006, "a Pfizer study of celecoxib in Alzheimer disease, which was completed in 2000 but not revealed until January 2005, showed an increase in cardiovascular risk with that drug. *See* Graham, D., Cox-2 Inhibitors, Other NSAIDs, and Cardiovascular Risk: The Seduction of Common Sense, JAMA, E 1-4, September 12, 2006. Indeed, in weighing the cardiovascular and gastrointestinal risk-benefit of Celebrex, purchasers, if they had been fully informed of the risks, could have reached the same conclusion as Dr. Graham, who questioned if "COX-2 inhibitors cost substantially more, confer substantially greater cardiovascular risk, and offer no unique and meaningful gastrointestinal tract benefit over generic naproxen plus proton pump inhibitor, is there any point to the continued use of these drugs?" *Id.* at E2. The promotion of Celebrex as safer than Vioxx is a main reason why Celebrex has achieved greater commercial success than Vioxx.

K. Defendants' Continued Unlawful Marketing Campaign Caused Overpayments by End-Payors for Celebrex

218. As a result of Defendants' claims, Plaintiffs and members of the Class purchased and/or paid for Celebrex even though a monthly supply was much more expensive than other NSAIDs.

219. To justify the disparity of Celebrex's pricing as compared to other NSAIDs and to ensure that physicians would prescribe and that End-Payors would purchase and pay for the drug, Defendants' misrepresented the safety and efficacy of Celebrex and omitted, concealed and suppressed the risks, dangers, and disadvantages of the drug through such misrepresentations, and engaged in promotion beyond that permitted by the FDA. Consequently, Celebrex captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2004 alone, sales of Celebrex exceeded $1.2 billion, despite the significantly higher cost of Celebrex as compared to other pain relievers in the same family of drugs.

220. Celebrex's deceptive and misleading marketing campaign resulted in overcharges to consumers and Third-Party Payors, such as Plaintiffs and the Class, for, in whole or in part, the costs of Celebrex. Millions of End-Payors, including consumers and Third-Party Payors, have

already paid for, and/or purchased and consumed Celebrex at prices based on the proposed wholesale price, which was about one hundred times the cost of generic aspirin. These End-Payors did not get the benefit of the bargain that Defendants held out to them and as a result End-Payors paid more than they would have or should have because Celebrex was promoted and advertised as a premium drug with reduced side effects for the purpose of deceiving consumers and End-Payors about Celebrex's adverse cardiovascular, and GI effects.

221. But for Defendants' unlawful conduct Class Members would have not purchased Celebrex and/or would have purchased a cheaper alternative. But for Defendants' unlawful conduct, Celebrex would not have been on formularies and thus would not have been purchased. Defendants knew that if they were successful in getting Celebrex on the formularies of TPPs based on deception that it would be difficult to change prescribing patterns of doctors unless the drug was withdrawn.

V. FRAUDULENT CONCEALMENT

222. Throughout the Class Period, Defendants affirmatively and fraudulently concealed its unlawful conduct from Plaintiffs and the Class.

223. Plaintiffs and the Class did not discover, and could not discover through the exercise of reasonable diligence, that Defendants had unlawfully concealed, omitted, and suppressed the serious adverse effects of Celebrex. Defendants conducted its unlawful activities in secret, concealed the nature of their unlawful conduct, and attempted to confine information concerning the adverse effects of Celebrex. Defendants attempted to withhold such information from Plaintiffs and members of the Class, the medical community, regulators and the public. Defendants fraudulently concealed its activities through various means and methods designed to avoid detection.

224. Plaintiffs and the Class could not have discovered Defendants' unlawful conduct at an earlier date through the exercise of reasonable diligence because Defendants actively and purposefully concealed their unlawful activities.

225. Defendants engaged in a successful, illegal fraud on consumers, Third-Party Payors and the general public, by which they deliberately and affirmatively concealed material

information on the risks, dangers, defects, and disadvantages of Celebrex, in at least the following respects:

a. By failing to disclose adverse effects of Celebrex to Plaintiffs, the Class, the medical community, and the public;

b. By ***disseminating only positive scientific data that implied*** to Plaintiffs, the Class, the medical community, and the public that adverse events did not exist;

c. By agreements among senior Pfizer, Pharmacia and/or Searle officials in meetings and in communications not to discuss publicly, or otherwise reveal, the totality of the adverse effects caused by Celebrex, Defendants' concealment of those adverse effects, and the nature and substance of other acts and communications in furtherance of Defendants' illegal scheme; and

d. By concealing studies showing increased risk of cardiovascular disease.

e. By falsely touting unsubstantiated benefits of Celebrex.

226. As a result of Defendants' fraudulent concealment, Plaintiffs and the Class purchased and/or paid for Celebrex and could not reasonably have discovered Defendants' misconduct regarding Celebrex prior to April 7, 2005. Plaintiffs and the Class therefore assert the tolling of any applicable statute of limitations affecting the rights of action of Plaintiffs and the Class.

VI. CLASS ACTION ALLEGATIONS

227. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, Plaintiffs seek certification of a national Class defined as follows:

> All End-Payors located in the United States, including Consumers and Third-Party Payors,[23] who purchased and/or paid for Celebrex not for resale during the period from December 1, 1998 through the present.
>
> Excluded from the proposed Class are (i) Defendants, any entity in which Defendants have a controlling interest or which have a controlling interest in Defendants, and Defendants' legal representatives, predecessors, successors and assigns; (ii) the judicial

[23] Third-Party Payors include all entities that: (a) provide, sponsor or insure a healthcare plan, which includes prescription drug coverage to natural persons, and (b) purchase, pay or insure all or part of the cost of prescription drugs prescribed and dispensed to those persons pursuant to a health plan.

officers to whom this case is assigned; and (iii) any member of the immediate families of excluded persons, (iv) governmental agencies, and (v) those who resold Celebrex.[24]

228. Plaintiffs also define state law subclasses as defined in the various courts set forth below.

229. The members of the Class are so numerous that joinder of all their members would be impractical. Celebrex has been prescribed to, paid for and ingested by millions of consumers nationwide.

230. There are questions of law and fact common to the Class that predominate over questions affecting only individual members, including, but not limited to:

a. Whether Defendants engaged in a fraudulent and/or deceptive scheme to portray Celebrex as a drug having superior qualities to other NSAIDs;

b Whether Defendants engaged in a scheme to create consumer demand for Celebrex based on deceptive statements concerning Celebrex's safety and efficacy;

c. Whether as a result of this scheme Celebrex was over prescribed;

d. Whether the price of Celebrex was inflated as a result of the scheme;

e. Whether Defendants are liable to Plaintiffs and the Class for damages under state consumer protection statutes;

f. Whether Defendants made material misrepresentations or material omissions about the cardiovascular risks associated with using Celebrex and regarding the effectiveness of Celebrex; and

g. Whether members of the Class are entitled to damages based on their payments for Celebrex, and, if so, the nature and amount of such damages.

231. Plaintiffs' claims and defenses are typical of the claims and defenses belonging to absent members of the Class, because Defendants have uniformly misrepresented that Celebrex is safer and more effective than traditional NSAIDs, overpromoted the benefits of Celebrex and uniformly failed to disclose the material cardiovascular risks associated with Celebrex.

[24] Plaintiffs have named class representatives for the Class, but have not named class representatives for every jurisdiction. Should the Court so require or direct, Plaintiffs are prepared to name proposed class representative Plaintiffs for every jurisdiction, or for each statewide class, and for each subclass the Court may designate.

Defendants' actions have deprived Plaintiffs and the members of the Class of their ability to make an informed decision about whether to pay for Celebrex, and if so at what price.

232. Plaintiffs will fairly and adequately assert and protect the interests of absent members of the Class, because Plaintiffs have retained counsel competent and experienced in complex class action litigation and have no interest adverse to any absent Class Members.

233. Class certification is proper under Federal Rule of Civil Procedure 23(b)(1)(A), because the prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications with respect to individual members of the Class and establish incompatible standards of conduct for Defendants.

234. Class certification is proper under Federal Rule of Civil Procedure 23(b)(1)(B), because the prosecution of separate actions by individual Class Members would create a risk of adjudications with respects to individual Class Members which would, as a practical matter, be dispositive of the interest of the other members not parties to these adjudications and/or substantially impair their ability to protect these interests.

235. Class certification is proper under Federal Rule of Civil Procedure 23(b)(2), because Defendants have acted, or refused to act, on grounds generally applicable to the Class, thereby making final injunctive relief or corresponding declaratory relief appropriate for the Class.

236. Class certification is proper under Federal Rule of Civil Procedure 23(b)(3), because common issues of law and fact predominate over any questions affecting only individual members of the Class, and a class action is superior to other available methods for the fair and efficient adjudication of this controversy.

237. The need for Class-wide notice does not provide a barrier to certification, in that notice can be effectively disseminated to Class by techniques customarily used in consumer class actions, including published notice, Internet notice and direct mailings based on readily available computer databases (such as the one Defendants used to send their "Dear Patient" correspondence).

FIRST CLAIM FOR RELIEF
(Violation of the State Consumer Protection Laws)

238. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein.

239. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the manufacture, promotion, and sale of Celebrex to Plaintiffs and the proposed Class Members.

240. As a proximate result of the Defendants' misrepresentations, Plaintiffs and the proposed Class Members have suffered an ascertainable loss, in an amount to be determined at trial.

241. Defendants intended that Plaintiffs and Class Members rely on their materially deceptive practices and purchase Celebrex as a consequence of the deceptive practices, including Defendants' misrepresentations and omissions of material fact in their marketing of Celebrex ***contrary to its FDA approved label***:

a. Defendants' promotions of Celebrex as a safe drug for the treatment of pain and as having fewer side effects than comparable drugs on the market were deceptive, unfair, and unlawful in that Celebrex was promoted as having both cardiovascular and gastrointestinal benefits over alternative NSAIDs, did not have such added benefits over NSAIDs, and was promoted solely for financial reasons and not due to any material increase in medical safety or efficacy over NSAIDs;

b. Defendants' conduct was unfair, unlawful, and deceptive in that Defendants knew Celebrex increased the risk of adverse cardiovascular events, such as heart attack and stroke, but promoted Celebrex as cardioprotective and safer than other, less expensive NSAIDs despite this knowledge and in violation of the scope of the approved FDA label;

c. Defendants' conduct was unfair, unlawful and deceptive by virtue of their manipulation of data and dissemination of such data to physicians in an effort to show that Celebrex was associated with a lower incidence of GI adverse events when compared to NSAIDs when this was not true.

d. Defendants' conduct was unfair, unlawful, and deceptive in that they touted the superiority of Celebrex for GI, CV efficacy in violation of the FDA label with knowledge that it was not superior to NSAIDs in the majority of patients;

e. Defendants portrayed Celebrex as a relief for symptoms and diseases without any statistically significant evidence for doing so and in contradiction to the FDA-approved label;

f. Defendants promoted the safety and efficacy of Celebrex above and beyond the safety and efficacy information in its FDA approved labeling in order to induce doctors to prescribe Celebrex and consumers and Third-Party Payors to purchase Celebrex at a price that exceeded its actual worth;

g. Defendants established Celebrex as a standard course of treatment based upon the use of reprints of articles appearing in prestigious medical journals which Defendants knew were false and/or misleading and contrary to its FDA approved label;

h. By causing the publication of an article in JAMA that suggested Celebrex had a superior GI effect when Defendants knew this was not the case and that the article was based on not all of the data and that the unreported data showed serious GI complications. Defendants knew this article was relied on by physicians and would create demand for Celebrex based on benefits that were not approved by the FDA. Defendants never corrected this article and their role in its publication and use is an unfair, deceptive and unlawful practice.

i. Defendants committed unlawful acts by promoting and advertising Celebrex in a manner that violated the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. §§ 331(a) and (b), 352(a), (f), and (n) and 355(a).

242. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state consumer protection statutes that allow Third-Party Payors to bring claims. Plaintiffs assert this claim on behalf of Third-Party Payors located in the states that permit TPP claims under the consumer protection laws as set forth below.

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. Code § 40.50.471, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*, including § 4-88-113(f), and § 4-8-102(5);

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.* and the Consumer Legal Remedies Act, Civ. Code § 1750 *et seq.* ("CLRA");

e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*, including § 6-1-113(1)(c) and § 6-1-102(b);

f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*, including § 42-110(a)(3);

g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*, including 6 Del. Code § 2512;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*, including § 28-390(1);

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*, including § 481A-2;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*, including § 48-602;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*, including § 13-101(h);

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*, including § 445-902(c);

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*, including § 407.010(5);

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*, including § 30-14-102(5);

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*, including § 59-160(1);

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*, including § 358-A:1(1);

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*, § 56:8-1(d);

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*, including § 51-15-01(4);

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*, including § 646.605(4);

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*, including § 201-2(2);

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*, including § 6-13.1(3);

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*, including § 39-5-10(9);

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*, including § 37-24-1(8);

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*, including § 47-18-103(9);

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*, including § 17.45(4);

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*, including § 59.1-198;

ll. Defendants have engaged in unfair competition or unfair, deceptive acts or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*, including § 19.86.010(1);

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*; and

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*, including § 40-12-102(a)(i).

243. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of various state consumer protection statutes that allow consumers to pursue claims. Plaintiffs thus assert this claim on behalf of Class Members in the states identified below and pursuant to the statutes identified below:

a. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. Code § 40.50.471, *et seq.*;

b. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

c. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.*;

d. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.* and the Consumer Legal Remedies Act, Civ. Code § 1750 *et seq.* ("CLRA");

e. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq.*;

f. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq.*;

g. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code § 2511, *et seq.*;

h. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of D.C. Code § 28-3901, *et seq.*;

i. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq.*;

j. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq.*;

k. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq.*;

l. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq.*;

m. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5.1, *et seq.*;

n. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, *et seq.*;

o. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.110, *et seq.*;

p. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 207, *et seq.*;

q. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

r. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

s. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Stat. § 445.901, *et seq.*;

t. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. § 325F.67, *et seq.*;

u. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Mo. Rev. Stat. § 407.010, *et seq.*;

v. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code § 30-14-101, *et seq.*;

w. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

x. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. § 598.0903, *et seq.*;

y. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

z. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq.*;

aa. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*;

bb. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*;

cc. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

dd. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code § 51-15-01, *et seq.*;

ee. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, *et seq.*;

ff. Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made representations in violation of Okla. Stat. tit. 15 § 751, *et seq.*;

gg. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq.*;

hh. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq.*;

ii. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq.*;

jj. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq.*;

kk. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq.*;

ll. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq.*;

mm. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq.*;

nn. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code Ann. § 13-1 1-1, *et seq.*;

oo. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, § 245 1, *et seq.*;

pp. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq.*;

qq. Defendants have engaged in unfair competition or unfair, deceptive acts or fraudulent acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq.*;

rr. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of W. Va. Code § 46A-6-101, *et seq.*;

ss. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq.*; and

tt. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-100, *et seq.*

244. Plaintiffs provided notice of this litigation as follows: On March 1, 2006, notice was sent to each Attorney General in each of the states requiring notice and where demand on a Defendant is required, such demand was made on March 1, 2006.

245. Pursuant to Section 1782 of the CLRA, in conjunction with the filing of this action, Plaintiffs have notified Defendants in writing of the particular violations of Section 1770 of the CLRA (the "Notice") and has demanded that Defendants refund the purchase price of Celebrex. Plaintiffs sent the Notice by certified mail, return-receipt requested to Defendants' registered agent of service/principal place of business in California.

246. As a direct, proximate and foreseeable result of Defendants' actions, Plaintiffs and members of the Class paid for higher priced Celebrex instead of purchasing a lower-priced generic and/or no pain medication at all.

247. If Plaintiffs and members of the Class had not been deceived concerning the safety and effectiveness of Celebrex, they would have taken steps so as to not purchase Celebrex at the prices set by Defendants. Among the possible steps is to exclude Celebrex from their approved schedules, set a lower scheduled value in the formulary, set a high co-pay obligation, and otherwise dissuade doctors from prescribing Celebrex.

248. Defendants' unlawful actions caused the purchase of, or payment for Celebrex by Plaintiffs, and as a result Plaintiffs paid more than they otherwise would have for NSAIDs: had a reasonable Plaintiff known the truth that Defendants misrepresented, Plaintiffs would have used and/or paid for another less expensive, equally effective, and at least as safe NSAID — many of which were available without a prescription and therefore would not have generated unnecessary physician visits with the unnecessary expense to Plaintiffs. Defendants would have lost a sale, and Plaintiffs would have avoided loss.

249. Plaintiffs and members of the Class were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at Third-Party Payors, physicians and consumers was to artificially create demand for Celebrex in lieu of other NSAIDs and/or caused Celebrex to command an artificially inflated price. Each aspect of Defendants' conduct combined to artificially create sales of Celebrex and/or to result in overpayments by Class Members.

250. As a direct and proximate result of Defendants' unfair methods of competition and unfair or deceptive acts or practices, Plaintiffs and the Class have suffered actual economic damage by paying for Celebrex in lieu of other cheaper NSAIDs and/or to pay at an artificially inflated price.

SECOND CLAIM FOR RELIEF
(Unjust Enrichment)

251. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein.

252. To the detriment of Plaintiffs and members of the Class, Defendants have been, and continue to be, unjustly enriched as a result of the unlawful and/or wrongful collection of, inter alia, payments for Celebrex.

253. Plaintiffs and members of the Class were injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at physicians and consumers was to artificially create demand for Celebrex at an artificially inflated price. Each aspect of Defendants' conduct combined to artificially create sales of Celebrex.

254. Defendants have unjustly benefited through the unlawful and/or wrongful collection of, inter alia, payments for Celebrex and continue to so benefit to the detriment and at the expense of Plaintiffs and members of the Class.

255. Accordingly, Plaintiffs and members of the Class seek full restitution of the Defendants' enrichment, benefits and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that:

A. The Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure with respect to Plaintiffs' claims for declaratory, equitable and injunctive relief, and Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages, and declaring Plaintiffs as representative of the Class and Plaintiffs' counsel as counsel for the Class; and designating such 23(c)(4)(A) class issues and/or 23 (c)(4)(B) subclasses as appropriate.

B. The conduct alleged herein be declared, adjudged and decreed to be unlawful;

C. Plaintiffs and the Class be granted an award of damages in such amount to be determined at trial, with trebled damages as provided by law;

D. Plaintiffs and the Class be granted an award of punitive damages in such amount to be determined at trial;

E. Defendants be enjoined from continuing the illegal activities alleged herein;

F. Plaintiffs and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law; and

G. Plaintiffs and the Class be granted such other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

VIII. DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial on all issues so triable.

DATED: January 5, 2007

Respectfully submitted,

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